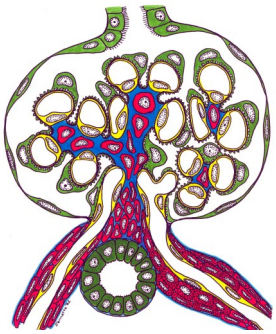
A Newsletter from the Glomerular Disease Collaborative Network

Kidney Care

Fall 2012

Approved by the UNC-CH Institutional review board



Health care professionals and patients working together to learn more about diseases that affect the filters (glomeruli) in the kidney.

Patient Perspective: Overcoming the Stumbling Blocks of Kidney Disease

By Jim Dineen

We've all read stories and articles where the first sentence starts out something like this: "Webster's Dictionary defines _____ as _____." I almost started this article like that when it struck me that I was the definition of the words I was searching for: Motivation and Exercise.

Now, don't think I'm all full of myself, because those who know me will tell you that you couldn't be farther from the truth. What made me realize who I am was realizing what I've been through and thinking and analyzing how I dealt with it and what my outcomes have been. I hope that some of what I have to share can help you.

"Boom!"
Did you ever think life just wasn't treating you right? Maybe things were just going along great and then Boom!--something happens to change your entire life's focus. Maybe you thought you had a handle on a particular problem or issue, and then one little change turns your world upside down.

My life has certainly been like that, and I must admit that sometimes I wondered who was out to get me... and why? I knew that wasn't really the case, but it just felt like no matter what I did, some stumbling block always jumped up and tripped me.

"My Mental Process"
What I've learned over many years and many tribulations is that the stumbling block was usually my mental process. Through trial and error, I've learned that the problems and issues I've faced in life were just that--a part of life, and I had to handle them to the best of my ability. I've found a whole lot of ability within myself, and so can you.

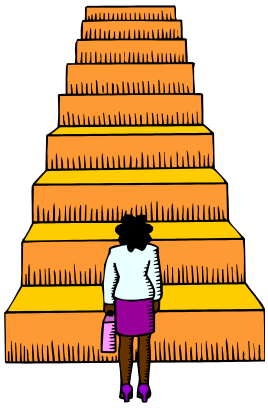
As I write this article, I realize that I'm eight years older than when I was diagnosed with kidney disease in 1998. I was shocked and overwhelmed. I'd never been sick in my life and had always taken care of myself. I was very physically active--a weight lifter and avid walker, played a lot of golf, and really enjoyed working in my yard. I ate right, and my weight hadn't varied more than five pounds in 20 years.

Motivated to "Win"
Kidney disease! What the heck was that? Here is where motivation kicked in. I didn't know it at the time, but my instincts told me that in order to deal with this new problem, kidney disease, I must attempt to understand it.

Once I was motivated enough to study my illness and try to understand what was going on with me, I began to feel empowered. The disease was affecting me in not so subtle ways, and I had to get control. The more in control I felt, the stronger I got, and the more I was motivated to "win" my new battle. ***Continued on next page...***

Patient Perspective Continued from Page 1

"Meet the Challenge"



When I was diagnosed in 1998 I was self-employed. I had owned my own Human Resource Consulting business since 1992, the year I resigned my corporate job to be my own boss. I lost my business, however, and lived on my savings and partial retirement income and my 401K until it was all gone. I then refinanced my house and now live in the "bank's house" for as long as I can make the payments.

Stumbling blocks come in all sizes. I'm not telling you all of this so that you can feel sorry for "Ole Jim." I've cried as much as anyone, screamed at the world more than most, and reminded God on more than one occasion that I just didn't deserve all this. The message that always came back was to "Meet the challenge."

The 10 Challenges

1. Study and know yourself and your foe. The first challenge is to know and understand your foe. Kidney disease, like many other barriers in life, needs to be understood so that we can know what we're up against.

I went to the Internet and read everything I could find on kidney disease. Most of it was foreign to me and in language I didn't understand. But one thing I was gaining on was knowledge, and when my doctors began talking to me in terms I didn't understand, I learned more. As scared as I was, I was getting to know my enemy.

2. Participate in your treatment, in your life. Challenge Number Two was a little more difficult. I had to do something with this knowledge. I began to ask questions of my medical team: What could I eat and drink without doing further damage? What had I done to make myself so sick? How could I be so sick and still feel so good?

You see, my disease was found by accident. I had no symptoms that I was aware of, so questions flowed from my lips like honey from a beehive. But, as I began to both understand my enemy and what I could do to help myself, I faced the next obstacle.

3. Never accept what is. Go for what might be. My third challenge was maybe the toughest. I had to get control of my mental situation and work at what was happening to me and move forward. I reached a point where I knew my disease and how sick I really was. I began to experience some pretty ugly side affects from both the disease and the medication.

During those years prior to going on dialysis, I had seven major surgeries and two biopsies. My weight varied weekly by as much as 15 pounds! I also experienced a draining of my abdominal cavity 41 times, and fractured both elbows and three ribs and had a concussion from falling in my bathtub! On top of that, I had fistula surgery just before I went on dialysis in 2000. I understand being sick, and, as blessed as I've been in my life, I've learned that all these situations were just stumbling blocks in a great life.

4. Embrace your sense of humor. Laughing feels so good. The fourth of my challenges was the easiest for me to deal with. I will be forever grateful to my friends and family for helping me keep my sense of humor.

I've had some rather harrowing experiences in my life. Through them all, I was encouraged by my parents and family to try and find the humorous side. That doesn't mean things weren't rough or that I didn't experience some pain, but I knew that most pain is short-lived (if you want it to be). Even having your abdominal cavity drained 41 times has a humorous aspect to it, if you look for it!

5. Exercise your body as well as your mind. Challenge number five was one of the most difficult for me. Paradoxically, it was also one of the easiest. I have exercised most of my life and know my body quite well. I know what I can and can't handle and have read all I could on which exercises could benefit me in my condition.

6. **Fight for what you want.** My most difficult challenge was getting my transplant approved. During the course of my illness, it was discovered that I also had contracted cirrhosis of the liver. I didn't really need another challenge, but it was mine, and I was going to overcome this one, too. *Continued on next page...*

Patient Perspective continued from Page 2

It took me a year and the support of my wife, my kidney donor, my daughters, brothers, father, and numerous friends to convince the transplant team that I could handle a new kidney without a liver transplant. My fear of not being accepted as a transplant candidate drove me to even more challenges, and each one became just another stumbling block to overcome. "One more block to step over!" became my personal motto.

7. Give something back.
Challenge Number Seven was my most interesting endeavor. I received my transplant in 2003 from my wife of 40 years, Joyce. The temptation to just drift off into the sunset and enjoy my rebirth was pretty strong, but, during the course of my illness, I had met so many wonderful people. I knew I had to give back to fellow patients, doctors, nurses, technicians, dietitians, social workers, friends, and family.

I found an organization that gave me this opportunity and am enjoying returning as many blessings as I can to others. My work with the Renal Support Network involves some of the most satisfying things I've ever experienced.

8. Nurture your spirituality. We all have it!
My eighth challenge was--and is for me--most important. I continued to develop my personal relationship with God, and that carried me through so much of my turmoil. When I had no one else to turn to, He was there. Whatever your spiritual persuasion, nurture it! I didn't win this battle by myself!

You are right now participating in Challenge Number Eight. The fact that you are reading this story says that you're somewhere in your series of challenges and is a testament to the fact that you can win. I still have kidney disease and will for the rest of my life. What I do with it is a new challenge every day. I've overcome so much that I feel stronger than I've ever felt in my life! I've found I can embrace physical, mental, and emotional issues in my life with a lightness, vigor, and determination that I never knew before.

9. Decide to move forward and then run.
Life really is a journey and not a destination. Therefore, as the commercial used to say: "Go for the gusto!" Remember that meeting the challenge takes work, but the reward is without description.

10. Live life one day at a time.
I live Challenge Number 10 beginning every morning when I awake. You can, too. I live life one day at a time.

Remember that your presence is a present to the world!

About the Author
Jim Dineen is a Vietnam veteran who has experienced a lot of ups and downs in his life, but nothing compared to kidney disease. He received a kidney from his wife, Joyce, and has worked with the Renal Support Network, the American Kidney Fund, and the Cincinnati Kidney Foundation. His story was featured in the June 2004 issue of Reader's Digest.

Reprinted with permission form Renal Support Network (RSNhope.org)

SEXUALITY & REPRODUCTIVE CONCERNS AFTER TRANSPLANT

Clara Neyhart, RN, BSN, CNN

Sexual function in both men and women generally improves after transplantation, although there are reports in the literature that one quarter to one third of patients continue to have some trouble with sexual function. This trouble may be related to fluctuating sex hormone levels, medication effects, endocrine disorders, depression and/or other medical conditions. Let's examine some of these causes of sexual and reproductive problems after transplantation, and considerations for pregnancy.

Premature menopause and infertility are not unusual in patients who have received cyclophosphamide (Cytoxan®) for treatment of autoimmune kidney diseases. It is not unusual for the medical team to suggest that men consider banking sperm prior to Cytoxan® therapy if possible. Changes in sperm count may be an issue. If you have received Cytoxan® and are trying to conceive, you may need to have some testing done to determine your reproductive capability. There are many fertility experts who address this issue.

Depression is among the most common causes of decreased sexual function in both men and women after transplant. While transplantation is often a very happy event, complications and stress may be a problem. New routines, concerns about rejection, readmissions to the hospital for complications, loss of employment, insurance problems, financial stress and changes in home life can all lead to depression. Sometimes, expectations of life after kidney transplantation are different from how things work out. Speaking with a counselor, social worker, psychologist, or psychiatrist through a private office, hospital, or county mental health department can be very helpful. Sometimes medications are needed to treat depression, and once depression is treated, the problems with sexual function may improve. You may need counseling yourself, but consider the possibility that you and your partner need counseling together.

Medications are often a cause of trouble with sexual function as well. Blood pressure medications, for example, can often cause trouble with sexual function. Often a change in medication can help. You should never stop a medication without talking with your health care provider, but keep in mind that some trouble with sexual function may be related to medications. It's worth a conversation with your nephrologist to go through your medications and determine if one or more medications are contributing to your problem.

Endocrine disorders such as diabetes or thyroid problems can cause trouble with sexual function. The better you control your diabetes, the better your whole body is going to feel! Diabetes can affect a lot of systems in the body that can add to problems with sexual function. Keep in contact with your doctor about how to control your diabetes. If you are on medication for thyroid problems, make sure you have your thyroid labs checked periodically as thyroid problems could also cause you not to feel well.

Sex hormone levels often improve with better kidney function. Most women who were not already post-menopausal resume their menstrual periods within a few months after transplantation, and are able to become pregnant fairly quickly.

This is why transplant teams and nephrologists counsel patients about pregnancy and contraception after transplant. Certainly one of the goals of transplantation is to have a normal life, including childbearing. However, there are safer times than others for a patient with a kidney transplant to consider pregnancy. Usually, the recommendation would be to wait at least a year following kidney transplantation to consider becoming pregnant. This is because the risk of kidney rejection is greatest in the first year, and generally, kidney function should be very stable when considering pregnancy. Most transplant centers will suggest that pregnancy is best considered when the serum creatinine is close to normal, around 1.4 mg/dl or less. This is different for every patient, and best addressed with your healthcare team, but generally, the lower the creatinine, the better chance for a healthy pregnancy for the mother, the baby, and the transplanted kidney. Blood pressure should be well controlled prior to pregnancy.

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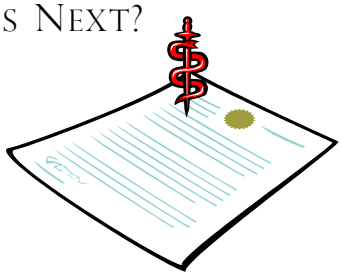
HEALTH REFORM & THE AFFORDABLE CARE ACT: WHAT'S NEXT?

Caroline Jennette Poulton, MSW



November Elections: The Republican Presidential nominee has promised to repeal health care if he is elected, but this may be easier said than done. It is more likely that parts of the health reform law will remain unfunded and implementation of newer provisions will slow down or stop altogether. If the current president is re-elected, health reform should move along as planned.

States Preparing for Health Exchanges: States continue to weigh their options on developing health care exchanges, and are expected to have a basic proposal in place or decide by January of 2013. Health exchanges will act as health care marketplaces for consumers looking to purchase individual health plans, and will also be used to enroll consumers in Medicaid and the Children's Health Insurance Programs. States can run their own exchange, or let the federal government run it for them. Starting in 2014, everyone is required to have insurance, and will use these exchanges to find coverage if they are not already covered through their employer or through public insurance like Medicare. Sixteen states have begun the process of setting up their own exchanges. To see where your state stands, visit: www.healthreform.kff.org.

Medicaid Coverage Expansion: As a result of the recent Supreme Court ruling, states now have the option of expanding Medicaid eligibility or leaving it as is. If a state decides to expand, starting in 2014 most people under the age of 65 with incomes at or below 138% of the federal poverty level (income of $15,415 for an individual in 2012) will be eligible.

Pre-Existing Conditions: Starting January 2014, insurance companies will not be allowed to refuse coverage because of an individual's pre-existing condition. Insurance companies will also not be allowed to charge higher rates due to a pre-existing condition. This provision may be especially important for transplant recipients who have had trouble getting coverage in the past.

For more information visit www.healthreform.kff.org or www.healthcare.gov

Sexuality & Reproductive Concerns Continued from page 4...

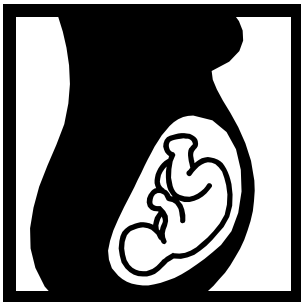
There are certain blood pressure medications which should not be used during pregnancy such as Enalapril®, so this requires a discussion with the physician. In addition, if a transplant patient is taking CellCept® or Myfortic®, these are usually discontinued and sometimes changed to Imuran®, an older, but similar medication which is considered safer for pregnancy. CellCept® has been shown to have dangerous effects on a fetus. There may be other medication changes needed as well, to protect the fetus. Kidney transplant patients are ideally followed in a high risk pregnancy clinic. Labs and blood pressure should be followed closely and more frequently during pregnancy. It is not uncommon for women with a kidney transplant to deliver early, on the order of around three weeks, although of course this varies. Both vaginal and cesarean deliveries are possible in women with kidney transplants. Women taking immunosuppression usually do not breast feed their children.

So what about contraception? Generally speaking, patients with kidney transplants can use most forms of contraception. Birth control pills are not a good choice for women who have uncontrolled high blood pressure or in women who have a history of blood clots. Women with normal blood pressure with no history of clots are able to take birth control pills if they monitor themselves closely for any change in their health. Otherwise, condoms, spermicidal foam or gel, and diaphragms are safe to use. Intrauterine devices (IUDs) are usually safe if changed periodically although there is a higher risk of infection in transplant patients. Patients using IUDs should see their gynecologist at least once per year to monitor the device. Finally, for some patients, sterilization by vasectomy or tubal ligation ("tubes tied") is an option. These are usually same day surgeries that are safe for transplant patients. After a discussion with your nephrologist, referral is made to a urologist for a vasectomy or a gynecologist for tubal ligation.

The main idea to remember about any of these concerns about sexual function or reproductive issues is to talk openly with your nephrologist to make sure that any therapy you choose is compatible with your other medications and medical conditions. You may be hesitant to bring up the subject, but this is considered part of your overall health and well-being, so speak up!

PREGNANCY, CHRONIC KIDNEY DISEASE (CKD) AND DIALYSIS

Connie Gilet, MSN



There are very few studies that examine the impact of kidney disease on mothers and babies during pregnancy. One study showed that pregnancy, even in the early stages of chronic kidney disease (CKD) (glomerular filtration rate between 60-89 ml/min), is associated with an increased risk of intrauterine ("in the uterus") growth restriction, premature birth and intrauterine fetal death (Alsuwaida et al, 2011). People with CKD who are thinking about getting pregnant should speak with a Nephrologist (kidney doctor) before becoming pregnant.

If the kidney disease has progressed such that the person is on dialysis, risks during pregnancy are even greater. It is rare to get pregnant while on dialysis (less than a 1% chance) and even rarer to deliver a live infant. The risks for intrauterine growth restriction, premature birth and intrauterine fetal death are even greater than those associated with early CKD. If a woman does become pregnant and maintains the pregnancy into in the second trimester, changes in nutrition, medication and dialysis are necessary and accompanied by much closer medical supervision.

Men who are on dialysis have lower sperm counts making it difficult for their partner to become pregnant. Women who are on dialysis do not have regular periods and have a very difficult time getting pregnant. If a pregnancy does occur, it usually results in a miscarriage. Because of irregular periods and the low chance of getting pregnant, some women do not use birth control. The use of birth control, however, is highly recommended if one is sexually active, since a pregnancy can result in medical problems or in the death of both the mother and/or infant.

There is little information to guide the selection of birth control in CKD. Oral contraception is usually not prescribed because it can increase blood pressure and can cause blood clots. Intrauterine devices (IUDs) carry an increased risk of infection. Tubule ligation for women ("tubes tied") and vasectomy for men (the tubes that transport sperm are "tied" off) are also forms of birth control and are permanent answers to preventing pregnancy. Condoms are the only non-permanent form of birth control that all people can use and have the additional benefit of protecting against sexually transmitted illnesses.

People with CKD who would like to get pregnant should discuss this with their nephrologist to receive information that is specific to his/her medical condition(s). Not being able to have children can produce a sense of loss and can cause depression and changes in self-image. Speaking with a counselor, social worker, psychologist, or psychiatrist through a private office, hospital, or county mental health department can be very helpful.

Reference: Alsuwaida, A., Mousa, D., Al-Harbi, A., Alghonaim, M., Ghareeb, S., & Alrukhaimi, M.N. 2011. Impact of early chronic kidney disease on maternal and fetal outcomes of pregnancy. *Journal of Maternal, Fetal and Neonatal Medicine,* 12, 1432-1436.

FOR PARENTS: KIDNEY DISEASE & ADOLESCENT SEXUAL HEALTH

Rose M. Sharpe, MSN, CPNP

Puberty is a time when a person becomes sexually mature. The physical change often occurs between ages 10 and 14 for girls and 12 and 16 for boys. African American girls can start puberty as early as age nine[1]. Openly addressing questions of sexual development and sexual desire are an important part of an adolescent's development of sexual identity. Sharing factual information and giving good moral guidance is vitally important in helping your adolescent understand him/herself. It is important for parents to teach their adolescent responsibility. This should include the process of making decisions and understanding what the consequences of their decisions will be. This discussion should start prior to puberty[2].

Adolescents often engage in risky behavior. The rates of sexual activity among high school students have increased since 2001, as have the rates of chlamydia and gonorrhea for both males and females 15-19 years of age[3].Thirty five percent of 14-19 year olds test positive for human papillomavirus (HPV), the virus linked to cervical cancer in women[4]. Parents should collaborate with their child and his/her healthcare provider if guidance is needed regarding sexual health. The child with chronic kidney disease still requires the same guidance as any other child.

If your child is sexually active, the best type of contraception depends on the suitability for your child's stage of kidney disease. Consultation with your healthcare provider is important.to determine the best method for your child's situation. It is important to remember that preventing pregnancy is not the only consideration. Preventing sexually transmitted diseases is also important and not all methods will accomplish both tasks. Parents should be aware that in some states, including North Carolina, your permission is not required for birth control to be prescribed for your adolescent if they request it. Early, open discussion with your adolescent is recommended.

Achieving sexual health requires more than just preventing unwanted pregnancies and sexually transmitted diseases. The goal of achievement of sexual health includes the ability to form and maintain meaningful relationships with others and one's body[5].

It is also is important to ensure that immunizations are kept up to date. Adolescents with chronic kidney disease should receive all recommended vaccines based on the Centers for Disease Control standard schedules[6,7]. The only exception occurs if the adolescent is immunosuppressed. In this situation no live vaccines should be administered. The available live vaccines include measles, mumps, and rubella (MMR), varicella, rotavirus, or live influenza. It is important to consult with your primary care provider to ensure that your child's immunizations are up to date.

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UPCOMING PATIENT MEETINGS/SUPPORT GROUPS

North Carolina/Raleigh VF Chapter Meeting
Date: Saturday, December 1, 2012
Time: Registration begins at 9:30 am
Meeting from 10:00 am to 2:15 pm, including lunch
Location: John Hope Franklin Center
2204 Erwin Road
Durham, NC

Highlights include:
* **Quality of Life Issues for People with Vasculitis—What are they? How do we address them?**
Speaker: Dr. Delesha Carpenter, Research Assistant Professor at UNC and researcher on vasculitis patient/family issues
* **Small Group Discussions**
The meeting includes time to talk one-on-one and in small groups with other vasculitis patients, family members and friends.

For further details and registration information:
Call Chapter Leader **Elaine Holmes** at **919-929-1246**; email: **eholmes18@nc.rr.com**
You can also access the group's website at: **http://ncvasculitissupportgroup.memberlodge.org/**

NephCure Foundation Seminars and Support Group Meetings

Are you or do you know someone affected by Focal Segmental Glomerulosclerosis (FSGS) or Nephrotic Syndrome? There is currently interest in your area for informational events and awareness about what is being done to combat Nephrotic Syndrome and FSGS.

Would you like to hear more about what NephCure can do to help raise awareness in your community? We are a growing team of patients and families that take action against these diseases by holding engaging events like FREE informational Lunch and Learn seminars, support group meetings, and NephCure Walks.

- ◊ The next NC NephCure Walk will take place on 10/13/2012 at Bond park in Cary. For more information or to find a walk near you, visit: www.thenephcurewalk.org
- ◊ The next NC Lunch & Learn will take place on 11/12/2012 at the Rizzo Conference Center in Chapel Hill. You can register online at http://www.nephcure.org/nephcure-lunch-learn-registration or contact Joselyn Cherry (information below).

LEARN about opportunities in your area to take action!

- ◊ Specific topics surrounding FSGS and Nephrotic Syndrome
- ◊ How NephCure can serve you as a resources

There are many levels of involvement, so you can determine what you'd like to do. Contact the person below to become connected. Let us help you and your community.

To find out more, contact Joselyn Cherry at 678-887-8287 or via email at jcherry@teamnephcure.org. You can also visit www.nephcure.org for more resources and a calendar of events.

RAVER : PROSPECTIVE, OBSERVATIONAL SAFETY STUDY OF PATIENTS WITH GRANULOMATOSIS WITH POLYANGIITIS(WEGENER'S) OR MICROSCOPIC POLYANGIITIS

Principal Investigator: Patrick Nachman, MD
Sponsor: Genentech, Inc.
Status: Enrolling

This is an observational study, also known as a non-experimental study or a registry study. An observational study looks at the results of the regular medical care of patients who have the same disease or are taking the same medication. You will not be asked to take an experimental drug or participate in any experimental procedures. You can participate in this study if you have granulomatosis with polyangiitis (GPA, formerly known as Wegener's granulomatosis) or microscopic polyangiitis (MPA) and are going to be treated with RITUXAN® (rituximab). Rituximab, in combination with glucocorticoids, is approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with GPA or MPA. Genentech, Inc. is the Sponsor of this observational study. Rituximab is being developed in collaboration with Biogen Idec, Inc.

The study will collect information for 4 years, about your treatment, your response to the treatment, the side effects and many other data about your health. There will be a screening visit, a baseline visit and then a visit every 6 months. Each visit will last between one to 2 hours.

For more information, please contact:
Anne Froment: (919) 966-2561 ext 247 OR email: anne_froment@med.unc.edu

OVERTURE: A MULTI-CENTER, LONGITUDINAL, OBSERVATIONAL STUDY OF PATIENTS WITH AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD) TO ESTABLISH THE RATE, CHARACTERISTICS, AND DETERMINANTS OF DISEASE PROGRESSION

Principal Investigator: Patrick Nachman, MD
Sponsor : Otsuka Pharmaceutical Development & Commercialization, Inc.
Status: Enrolling (Thank you to the 14 volunteers already in the study!)

Description: This research study will investigate a correlation between the rate of kidney enlargement and the decline of kidney function in Autosomal Dominant Polycystic Kidney Disease (ADPKD) patients to see if the change in the volume of the kidneys could be used as a prognostic marker of disease progression. This is an observational research study: no drug will be tested.

Inclusion criteria

- Men and women 12 to 70 years, inclusive
- Existing diagnosis of ADPKD
- Total kidney volume ≥ 300 cc/m height by ultrasound (within 1 year prior to baseline) or ≥ 250 cc/m height by MRI (within 1 year prior to baseline)

Exclusion Criteria

- Any medical condition that could interfere – in the opinion of the study doctor- with evaluation of the research study objectives (for example: inability to have an MRI)
- Current or expected (within the next six months) interventions for the treatment of ADPKD affecting kidney volume (for example, cysts reduction) without the prior approval of the sponsor

For more information, please contact:

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PLASMA EXCHANGE AND GLUCOCORTICOID DOSING IN THE TREATMENT OF ANCA-ASSOCIATED VASCULITIS: A MULTICENTRE RANDOMIZED CONTROLLED TRIAL (PEXIVAS)

Principal Investigator: Patrick Nachman, MD
Sponsors: Food and Drug Administration
Status: Enrolling *(Thank you to our first two volunteers!)*

Description: Multi-center, international, open label, factorial design, randomized control research study in severe Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-associated vasculitis (AAV) to determine the efficacy of plasma exchange (PLEX) in addition to immunosuppressive therapy and glucocorticoids (GC) in reducing death and end-stage renal disease (ESRD) and to determine the non-inferiority of a reduced dose glucocorticoids (GC) regimen in reducing death and ESRD.

This research study will randomize patients to receive either PLEX or no PLEX and to receive either a standard glucocorticoid (GC) dose or a low GC dose. All patients will receive standard immunosuppressive induction therapy with cyclophosphamide or rituximab. Your participation to the research study will last between 2 and 7 years. The exact duration for the subject will depend on how long the research study has been running before you are recruited. We anticipate recruiting for 5 years.
You will need to visit the clinic 7 times within the first year and then every 6 months until the end of the research study (minimum 9 - maximum 19 visits in total). Each visit will last approximately half an hour.

Patients will be followed more frequently when they begin the research study when the interventions are most intense and treatment is designed to induce remission of disease (Induction of Remission Period) and follow-up will be less intense after this period (Maintenance of Remission Period).

Inclusion Criteria

- Patients must meet all of the following criteria:
- Vasculitis with a diagnosis of microscopic polyangiits (MPA) or Granulomatosis with polyangiitis (GPA, Wegeners)
- A kidney biopsy showing evidence of the disease
- Hematuria (blood in the urine)
- An estimated glomerular filtration rate <50
- History of pulmonary hemorrhage (bleeding in the lungs) caused by vasculitis

Exclusion Criteria

- Patients must have none of the following:
- A diagnosis other than MPA or GPA
- A positive serum test for anti-glomerular basement membrane or a renal biopsy showing linear glomerular immunoglobulin deposition
- Receiving a dialysis treatment for greater than 21 days prior to randomization
- Age <15 years
- Pregnancy
- Inability or unwillingness to comply with birth control/abstinence
- Inability to provide informed consent
- Treatment with cyclophosphamide, prednisone, and/or rituximab within the last 28 days
- A comorbidity that, in the opinion of the investigator, excludes you from the study treatment

For more information, please contact:

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A RANDOMIZED, PLACEBO-CONTROLLED, PARALLEL-GROUP, DOUBLE-BLIND STUDY OF H.P. ACTHAR® GEL (ACTHAR) IN TREATMENT-RESISTANT SUBJECTS WITH PERSISTENT PROTEINURIA AND NEPHROTIC SYNDROME DUE TO IDIOPATHIC MEMBRANOUS NEPHROPATHY (IMN)

Principal Investigator: Vimal Derebail, MD
Sponsor: Questcor Pharmaceuticals, Inc.
Status: Enrolling

Description: The purpose of this research study is to look at the safety and effectiveness of the study drug Acthar as compared to Placebo (inactive product) in patients who have been diagnosed with idiopathic nephrotic membranous nephropathy. Acthar is a long-approved drug used to treat patients with proteinuria, multiple sclerosis and infantile spasms. The drug is given by injection under the skin.

Participants: Patients with idiopathic membranous nephropathy with a low chance of remission and who have previously been treated with standard treatment without success (treatment-resistant).

Length of the study: Up to 14 months

Inclusion criteria:

- Male or female between 18 and 75 years of age
- Body mass index (BMI), which is a tool for measuring weight and height, of less than or equal to 40kg/m2
- If you are being treated for high blood pressure, your blood pressure must be 140/80 mmHG or lower
- Documented history of nephrotic syndrome due to Idiopathic Membranous Nephropathy (iMN) in the last 4 years
- Your blood and urine test results must meet certain levels
- You must be taking one or more medications for iMN for at least 6 months, please talk to the study doctor about the medications you are taking.
- History of iMN that did not become better after using one or more medications for iMN
    a. If you stopped taking this therapy because of a change in your health or bad side effect before you could tell if you were getting better or not, you may still eligible
    b. If you got better or almost got better taking this medication(s) and then had a relapse of your disease, you will not be eligible

Exclusion Criteria

- Unwilling to receive subcutaneous injection
- Contraindication to the use of the drug, as mentioned on the package insert (for example; osteoporosis or peptic ulcer or congestive heart failure)
- Type 1 or type 2 diabetes
- History of deep vein thrombosis (DVT) in the past 6 months
- Pregnant or breastfeeding or unwilling to use birth control during the study
- History of heart problems
- Other exclusion criteria as assessed by the study doctor

For more information, please contact:

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NEPHROTIC SYNDROME STUDY NETWORK (NEPTUNE)

The five-year NEPhroTic Syndrome StUdy NEtwork (NEPTUNE) is studying adults and children with protein in their urine, with a focus on three kidney diseases: Focal Segmental Glomerulosclerosis (FSGS), Minimal Change Disease (MCD) and Membranous Nephropathy (MN).

Volunteers for the study must have a clinical need for a kidney biopsy and fit other requirements such as having a certain level of protein in their urine. Participants in the study will be asked to provide kidney tissue from the biopsy, nail clippings, blood and urine samples, and to give information about their medications, health, and quality of life at regular interval (4 times the first year, 2 times a year after that). All samples and information will be used for research on these kidney diseases with the hope to learn more about risk factors and markers of the disease, how to manage symptoms of the disease, and eventually development of better treatments.

UNC is one of 15 participating sites in the United States and Canada conducting the research over the five years of the project. As of August 2012, a total of 303 volunteers from all sites have become a part of the study, with 29 participating from UNC. Thank you to all who have agreed to be in the study!

Frequently Asked Questions:

I have had a biopsy and have been diagnosed with FSGS a year ago. Can I participate in the study?
No, NEPTUNE only enrolls new patients, at the time of their renal biopsy, allowing for the standardized collection of tissue, blood and urine, along with a comprehensive patient history. However, you can enroll in the NEPTUNE Contact Registry to be contacted in the future about clinical research opportunities and updates on the progress of related research projects (https://rarediseasesnetwork.epi.usf.edu/NEPTUNE/register/registry.htm).

Will I test a new drug?
No, this is a study to collect information and is not a treatment study. You will continue to see and be treated by your nephrologist.

Who should I contact to have more information or enroll?

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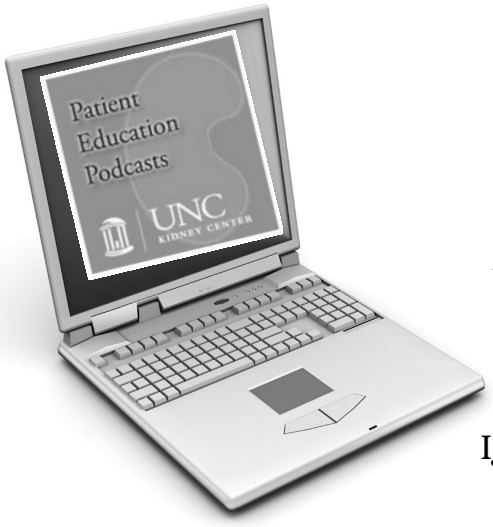

For more kidney disease information, internet links, and printable copies of this newsletter, check out

our website: **www.unckidneycenter.org**

Also be sure to check out our glomerular disease patient education recordings at:

http://www.unckidneycenter.org/podcast.html

We now have recordings for ANCA, FSGS, Fibrillary GN, IgA Nephropathy, Minimal Change Disease, Membranous Nephropathy, and more!

VENUS THROMBOSIS IN ANCA VASCULITIS

Principal Investigator: Patrick Nachman, MD
Funding Source : National Institutes of Health
Status: Enrolling *(Thank you to the 25 UNC participants who are already enrolled!)*

Description: Patients with Anti-Neutrophil Cytoplasmic Autoantibody (ANCA) -associated vasculitis can form blood clots in the deep veins of the body (usually the legs) more than the general population. These deep vein "thrombi" (clots) or "DVT" can obstruct a deep vein such as the femoral vein in the leg and cause swelling and pain. Sometimes, a small piece of the clot can break away, and travel through the heart and get caught in the lung. This is called a "pulmonary embolus" which can severely impair the ability to oxygenate the blood, and can lead to severe respiratory distress and sometimes death. The purpose of this research study is to learn why patients with ANCA vasculitis are at greater risk of forming these blood clots than the general population, and specifically to test whether the presence of certain antibodies in the blood called "anti-plasminogen antibodies" are associated with developing a DVT. One of the roles of plasminogen is normally to dissolve clots. It is thought that the presence of anti-plasminogen antibodies delays the dissolution of small clots, and allows bigger clots to form. The researchers want to see if detecting the presence of antibodies attacking plasminogen can help to predict who is at risk for DVT, and to assess the feasibility of a screening protocol for blood clots. The study lasts one year and includes 5 visits. Ultrasound of the legs might be done if you seem at risk for blood clots based on the study doctor assessment.

Inclusion Criteria

- Age ≥18
- Diagnosis of active ANCA disease
- Active disease as indicated by a BVAS of ≥ 5 with either de novo or relapsing disease
- Presence of inflammation (measured by the D dimer lab test) or presence of anti-plasminogen antibodies

Exclusion criteria:

- Pre-existing need for chronic anti-coagulation (e.g. atrial fibrillation, mechanical cardiac valve replacement, etc.)
- Bilateral lower extremity amputation precluding the use of compression ultrasonography

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CYCLOPHOSPHAMIDE-RELATED UROTHELIAL TUMOR EVALUATION

Principal Investigator: Patrick Nachman, MD
Status: Enrolling

Description: The purpose of this research study is to create a registry of patients who have received treatment for vasculitis or glomerulonephritis with the chemotherapy drugs cyclophosphamide (Cytoxan) or chlorambucil. These drugs are known to increase the risk of bladder cancer. For this reason, screening for bladder cancer is recommended although specific guidelines as to the frequency of such screening are not well established. Although screening for bladder cancer is offered to patients previously treated with cyclophosphamide or chlorambucil, the optimal screening method and frequency are not established.

The specific aims of the registry are to:

1. Identify patients who have been treated with cyclophosphamide or chlorambucil and are at risk for bladder cancer.
2. Offer these patients a systematic screening regimen with scheduled cystoscopies.
3. Collect demographic, clinical, and epidemiologic data on factors susceptible to influence a patient's risk for bladder cancer.
4. Assess the utility of a cytology test on voided urine in detecting a bladder cancer.

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A RANDOMIZED, DOUBLE-MASKED, PLACEBO-CONTROLLED, MULTICENTER, PHASE 2 STUDY TO EVALUATE THE SAFETY AND RENAL EFFICACY OF LY2382770 IN PATIENTS WITH DIABETIC KIDNEY DISEASE DUE TO TYPE 1 OR TYPE 2 DIABETES

Principal Investigator: Amy Mottl, MD
Sponsor : Eli Lilly and Company
Status: Enrolling

Description: The purpose of this research study is to learn about a new drug named LY2382770 to see if it is safe and if it helps to slow the progression of chronic kidney disease (CKD) in patients with diabetes. Diabetes frequently causes damage to the kidneys. Diabetic kidney disease results in protein loss in the urine and/or decreased ability of the kidneys to get rid of the toxins that are normally produced in the body.

To slow that progression, 2 kinds of drugs can be used: Angiotensin-Converting Enzyme Inhibitor (ACEi) such as Enalapril (Vasotec®), Lisinopril (Prinivil®, Zestril®), and Ramipril (Altace®); and Angiotensin II Receptor Blocker (ARB) drugs such as Irbesartan (Avapro®), Losartan (Cozaar®) and Valsartan (Diovan®). It would be helpful to find new drugs that slow the loss of kidney function even more, or even stop that progression.

The study involves coming to UNC Hospitals for 19 visits over 14 months: one screening visit, 12 treatment visits and 6 follow-up visits. Each participant will be assigned either to the study drug group or to the placebo group. At each treatment visit, participants will receive one dose of the new monoclonal antibody LY2382770 or a dose of placebo, depending on the group he/she has been assigned to. The dose is given by an injection under the skin.

Inclusion criteria

- Men and women 25 years of age or older with a diagnosis of type 1 or type 2 diabetes mellitus
- A diagnosis of Diabetic Kidney Disease (diabetes plus reduced kidney function)
- Stable use of blood pressure medication and acceptable blood pressure

Exclusion Criteria

- Inability or unwillingness to comply with birth control/abstinence, if you are a female of childbearing age
- Please call one of the study coordinator for more exclusion criteria

For more information, please contact:

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A PHASE 2, MULTICENTER, RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND, PLACEBO-MASKED, PARALLEL-GROUP PILOT TRIAL TO COMPARE THE EFFICACY, TOLERABILITY, AND SAFETY OF TOLVAPTAN MODIFIED-RELEASE AND IMMEDIATE-RELEASE FORMULATIONS IN SUBJECTS WITH AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE

Principal Investigator: Patrick Nachman, MD
Funding Source : Otsuka Pharmaceutical Development & Commercialization, Inc
Status: Enrolling *(Thank you to the 2 UNC participants who are already enrolled!)*

Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC)) is studying an investigational drug called tolvaptan ("Study Drug"). An investigational drug is a drug that is being studied for approval by the United States Food and Drug Administration (FDA). Tolvaptan (Samsca®) is a drug approved for use in the United States (2009) in patients with certain types of hyponatremia. Hyponatremia is low amount of sodium or salt in the blood. Tolvaptan (Samsca®) is approved in the European Union (2009) for treatment for a specific type of hyponatremia (hyponatremia due to "syndrome of inappropriate antidiuretic hormone secretion" (SIADH)

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RECIPE BOX: HOMEMADE PIZZA

Diet type: ☑ CKD non-dialysis ☑ Dialysis ☑ Diabetes

Recipe submitted by DaVita dietitian Victoria from Illinois.
Portions: 12 **Serving Size**: 1 Slice (1/12 of pizza)

Ingredients

- 1/2 package (1-1/4 teaspoon) dry yeast
- 1-1/2 cups warm water (divided use)
- 2 tablespoons olive oil (divided use)
- 1 tablespoon sugar
- 2 cups white all-purpose flour
- 3 ounces low sodium tomato paste
- 1/4 teaspoon garlic powder
- 2 tablespoons Italian seasoning
- 1/2 pound cooked ground beef or pork, well drained
- 1/4 teaspoon black pepper
- 1/4 teaspoon crushed red pepper
- 1/4 cup raw onion, chopped
- 1/4 cup green pepper, chopped
- 6 ounces mozzarella cheese, shredded

Preparation

1. Dissolve yeast in 1 cup warm water. Stir in 1 tablespoon olive oil, sugar and flour to make dough. Place in a greased bowl, cover and set aside.
2. Combine tomato paste, 1/2 cup water, garlic powder, Italian seasonings and remaining oil in a small saucepan and simmer 5 minutes.
3. Brown meat with black and red peppers in a skillet. Drain off fat. Add onion and green pepper.
4. Grease a 17" x 14" baking sheet or pizza pan. Press dough onto sheet. Spread sauce, meat mixture and cheese over dough. Bake at 425° for 20 minutes or until dough and cheese are golden brown.
5. Cut into 12 servings.

Nutrients per serving

Calories 201
Protein 11 g
Carbohydrates 19 g
Fat 9 g
Cholesterol 25 mg
Sodium 75 mg
Potassium 176 mg
Phosphorus 115 mg
Calcium 118 mg
Fiber 1.4 g

Helpful Hints: Each pizza slice has 1/2 ounce of cheese to keep phosphorus low.

Renal & renal diabetic food choices: 1 meat, 1 starch, 1 fat, 1 vegetable, low potassium

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Tolvaptan – Continued from page 16

The Study Drug has not been approved for sale in the United States to treat Polycystic Kidney Disease (PKD). PKD is a disease that causes kidney cysts (fluid-filled balloons), worsening kidney function, blood in the urine, kidney pain, high blood pressure, kidney stones, kidney infections, and cysts in the liver or other parts of the body and sometimes heart or blood vessel abnormalities. Tolvaptan is being studied as a possible treatment for PKD. For those with PKD, the kidneys respond abnormally to the hormone vasopressin that may be involved in cyst development or growth in humans. Tolvaptan interferes with vasopressin's effects on the kidney, and when taken regularly, appears to block cyst growth in animal models of PKD. It is hoped that similar effects will be seen in humans. Tests will tell how useful tolvaptan will be in treating PKD.

There are two different formulations that exist for tolvaptan. One formulation is a tablet that releases the drug substance immediately. The second formulation is a capsule that is designed to release drug substance more slowly over time. This study will use both the immediate release tablet and the modified release capsule, to compare the efficacy, safety and tolerability of both formulations with a placebo (a pill or a capsule that does not contain any medication).

A total of approximately 180 people at approximately 20 institutions will take part in this study, including approximately 36 people from UNC. (Thank you to the first 2 volunteers enrolled in the study!) The expected duration for trial participation, including Screening, Treatment, and Follow-up periods is 13 weeks. Treatment duration is expected to be 8 weeks. The study involves three Magnetic Resonance Imaging (MRI) scans, without contrast; two 24hours urine collections; two 24hours blood pressure monitorings, and the use of an electronic diary to keep track of voids and study drug ingestion.

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