A Newsletter from the Glomerular Disease Collaborative Network

Kidney Care

Fall 2013

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.

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Peer Perspective: Managing multiple medications

By Lori Hartwell

I have taken enough pills in my lifetime to choke several horses! (I am sure you have taken your fair share, too.) At this point, I believe that my 42 years of pill taking have qualified me for a PhD in pillology, so I thought I would share a few tips that I have learned along the way. There are a lot of issues that I could cover, but for now I will limit my comments to two general categories—medication safety and medication adherence.

It is always important to check your medications when you get them to make sure the pharmacy didn't inadvertently give you the wrong prescription. This has happened to me on more than one occasion and is a definite safety and health concern.

Once you have the right medications, you need to decide where to store them. The bedroom (not the bathroom medicine cabinet) is one of the best places to keep medications because it is likely that the temperature and humidity will be more constant. Changes in temperature, humidity, and exposure to light can sometimes cause medications to become ineffective or dangerous.

When deciding where to store your medications, you also want to make sure to consider the safety of others in your household. If you have children or pets, make sure that the medications are out of their reach (remember that for children the definition of "out of reach" changes with age). If you have houseguests, you may want to consider whether you should temporarily put your medications in a different location. Adherence to the prescribed medication schedule is also vitally important. Taking the right medication at the right time at the right dose is an acquired skill. Adherence ensures transplant and dialysis success!

Right now, I have 14 bottles of medications on my bedroom dresser (I obviously have no children or pets that can reach them). For me, having the meds visible reminds me to take them. To help me organize my prescription bottles, I label the top of my medications with colored happy face stickers. For example, I use green for morning, yellow for lunch, and red for nighttime. I use an additional orange sticker to identify blood pressure medications, and a purple sticker to identify "as needed" medications.

It is vital to know the correct time to take each medication, and each medication can be different. For example, phosphate binders need to be taken with meals and snacks. If a medication makes you sleepy, ask your doctor if it is possible to take it at bedtime. Some meds may also need to be taken on an empty stomach. Transplant meds must be taken at the same time each day to maintain constant levels in the bloodstream. Oftentimes the directions on prescriptions are not very clear. For example, the label may simply state "take twice a day" without providing guidance about the best time of day. If you have questions about when to take your medications, you should check with your doctor. *Continued on Page 2*

Managing Medications Continued…

I take most of my meds either in the morning when I get up or at bedtime, so I have not found a need to set an alarm for those times. I do set my phone with an alarm to remind me when to take my lunchtime medications. It may be a good idea for you to set an alarm for all medication times if you are new to the whole pill popping game. Taking phosphate binders with every meal can also be a challenge, but I have found that the key is to have them everywhere—I have them on the dining room table, in my purse, and on my desk.

Learning to order medications properly is another necessary skill. Often medications have different refill dates, so you may feel like you are continuously ordering prescription refills. Consider the following when managing your refills. For each medication, you should ask yourself questions such as: How many refills do I have left? Do I need to get any blood tests before ordering my refill? Do I need to talk things over with my healthcare team before ordering refills? How long does it take to get my medication? For example, my insurance company requires me to get many of my medications by mail order, which can take up to 10 days. Be on the ball to make sure you aren't paying overnight shipping fees.

When calling in a mail order refill and dealing with the frustration of an automated system you may need to play soft music and have a puppy on your lap to pet and calm your nerves. On many occasions I have found myself yelling "operator" like a mad woman in the receiver, hoping that their voice recognition system would understand my words, only to be prompted back to the very beginning. I have learned that, for the mail order house I use, using the term "representative" instead of "operator" is the key to talking to a human being. Although mail order pharmacies are a reality for many of us, I like going to the corner drug store whenever possible. Besides being easier, you can have face-to-face contact with an actual pharmacist, and you can check your meds on the spot.

I always keep a medication list in my wallet and in my Smart Phone. It is not only impossible to remember all the names, times and doses, but I also impress healthcare professionals when I whip out the list. I also have given this list to my family in case of an emergency. A great website called MyMedSchedule.com has helped me create, update and print my list of meds—it also provides some pictures of the medications.

Finally, if you have any questions about your medications at any time, don't be shy about asking your doctor. There are undoubtedly many more tips that I could provide on medication safety and adherence, but my time has run short— I need to go take my meds!

Lori Hartwell is the founder of the Renal Support Network, a nonprofit, patient-focused, patient-run organization that provides nonmedical services to those affected by chronic kidney disease. A kidney patient since age two, she has survived 40 plus surgeries, 13 years of dialysis and is now living with her fourth kidney transplant.

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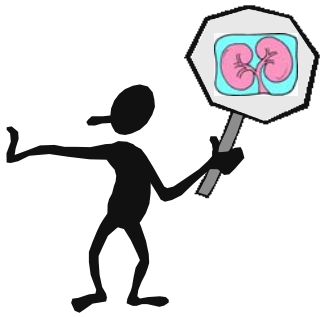
PROTECTING YOUR KIDNEYS! MEDICINES & SUBSTANCES TO AVOID AND WHAT IS OKAY TO TAKE

By Jenny Hawley, MSN, FNP-BC



When you have kidney disease, it is important to avoid potentially harmful medicines and substances that could cause damage to your kidneys. This article will provide you with a list of medicines found in your local drugstore that you should avoid taking if you have kidney disease. It will also review other substances to avoid in order to protect your kidney function. As always, please contact your kidney doctor (nephrologist) or nurse if you have specific questions regarding the safe use of any medicines.

The first group of medicines to avoid or use with caution are ***NSAIDs*** (Non-Steroidal Anti-Inflammatory Drugs) such as Ibuprofen (Advil or Motrin), Naproxen (Naprosyn or Aleve), and aspirin (unless prescribed by your doctor). These medicines may be included in over-the-counter (OTC) multi-symptom cold and cough remedies. So, it is important to read the entire list of ingredients on medicine labels. You should avoid taking ***decongestants*** used for cold symptoms such as Pseudoephedrine (Sudafed) if you have high blood pressure (BP) or hypertension since these medicines can raise your BP. Use caution if taking ***antacids and laxatives*** with magnesium, phosphorus and aluminum such as Mylanta, Milk of Magnesium, Amphogel, and Fleets products since these substances may not be filtered well by your kidneys and can build up.

Other substances to avoid or to use with caution are herbal medicines and remedies as well as vitamin and food supplements since the effects of these agents are unknown and they could cause damage to your kidneys. If you are told that you need a CT scan or MRI scan, please alert doctors and nurses that you have kidney disease if you go to the Emergency Room (ER) or go to see another doctor. You probably should not receive contrast dye that is put in your veins since the contrast could harm your kidneys. Lastly, if you have kidney disease, you may need to avoid using salt substitutes such as LoSalt and No Salt since they contain potassium. These agents can lead to higher potassium levels which could be dangerous for your heart.

So… what medicines can you take safely when you have kidney disease?

- For pain, you can take Acetaminophen (Tylenol) or products containing Tylenol as long as you do not exceed the recommended total daily dosage listed on the medicine label.
- For a stuffy nose or cold symptoms, you can try using saline nose drops or spray. Lozenges and menthol products (Vicks, for example) can also help with cold symptoms. There are several OTC cold and cough preparations that are made for people with high blood pressure; your pharmacist should be able to recommend a product. Claritin, Zyrtec or Allegra can be used for seasonal allergies.
- For indigestion symptoms, it is fine to try Prilosec OTC (over the counter).
- For constipation, start with trying stool softeners and you can add Miralax (available OTC) if needed.
- For mild occasional diarrhea, Loperamide (Imodium) can be taken.

A Note about Antibiotics: If you need to receive any antibiotics and you have reduced kidney function, the dose of your antibiotic may need to be decreased for your lower kidney function. Some antibiotics are safe to take when you have kidney disease and others should be avoided. It is best to check with your kidney doctor (nephrologist) about the possible need for dosage adjustment.

SAVE YOUR VEINS! UNDERSTANDING VASCULAR ACCESS

By Fernanda Payan Schober, MD

A part of living with kidney disease is planning for the future. This means planning for the day when you may possibly need dialysis to clean your blood. Vascular access is a "lifeline" for hemodialysis as it is how your blood is accessed so that it may be transferred to a dialysis machine to be cleaned. There are three types of vascular access: fistulas, grafts and catheters, with fistulas being the superior option.

An arteriovenous (AV) fistula is a blood vessel that is created by a surgeon who links one of the arteries in your arms or legs to one of your veins. By joining the artery to the vein, one large blood vessel is formed that can be used for dialysis. If the surgeon cannot connect the artery directly to the vein, then a graft (which is a piece of synthetic material) may be used to make the connection. A catheter is different from an AV graft or fistula as it is like a large IV that goes into a vein in your neck and hangs from your chest wall.

Unlike an AV graft or catheter, an AV fistula remains underneath your skin and does not involve any foreign material. So, this makes AV fistulas the best choice for vascular access as they can last for years and have the fewest complication rates. In fact, patients who dialyze with an AV fistula are 15 times less likely to get a vascular access related infection than patients who use a catheter for dialysis. There are a limited number of veins and arteries in your arms, so it is important that you take steps to protect these places that can serve as potential sites of future vascular access.

Vein preservation means not allowing anyone to do anything that can damage your veins. Veins can be damaged by having blood drawn from them when you are getting blood work done, or when IVs are placed to administer medications. Placement of long-term use IVs that are called PICC lines (PICC stands for Peripherally Inserted Central Catheter) should also be avoided in patients with chronic kidney disease because they can damage the arm veins as well.

Unfortunately, phlebotomists are not often aware about the importance of vein preservation in patients with chronic kidney disease, or may not simply know your level of renal function. So, it is important that you be your own advocate. Ask your phlebotomist to save your arm veins and restrict lab draws to the back of the hands. Likewise, if you must have an IV placed, ask that it be placed in the back of your hand.

AV fistulas are the best vascular access, so it is important that you have that option if you need dialysis. Knowledge is power, so it is important to empower yourself by knowing your vascular access options and preparing for the day when you may need dialysis.

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[1] "Fistula or catheter: The patient's perspective." Fistula First. 2009. Web. 2 Sept 2013. http://tinyurl.com/avfistula

[2] Hoggard, Jeffery. Seminars Dial.2008 Mar-Apr;21(2):186-91

RECENT PUBLICATIONS USING GDCN REGISTRY DATA

Thanks to your generous participation in our patient registries, we are able to conduct a wide range of studies to help further our understanding of glomerular diseases. See below for some of our most recent publications. To read more, you can look up these articles on www.pubmed.com.

Carpenter DM, Hogan SL, DeVellis RF. (2013) Predictors of medication non-adherence for vasculitis patients. Clin Rheumatol. 2013 May;32(5):649-57 . PMCID: PMC3743237.

Dr. Carpenter and colleagues conducted surveys with vasculitis patients to learn more about medication non-adherence. Younger age, female sex, experience of side effects and symptoms of depression were all associated with medication non-adherence. This data will help health care providers know who is more at risk for not taking medicine appropriately.

Free ME, Bunch DO, McGregor JA, Jones BE, Berg EA, Hogan SL, Hu Y, Preston GA, Jennette JC, Falk RJ, Su MA. ANCA Disease Patients Have Defective Treg Function Exacerbated by Presence of a Suppression-Resistant Effector Population. Arthritis and Rheumatism. 2013 Jul;65(7):1922-33. PMCID: PMC3717615

Investigators used blood samples collected in clinic to look at a key protein (FOXP3) which helps regulatory T cells (a type of immune or white blood cell) dampen inappropriate inflammation in healthy individuals. In ANCA disease, this FOXP3 protein is missing a segment and may explain why regulatory T cells in ANCA disease cannot control autoimmune inflammation. Additionally, these same studies discovered a population of T cells that is increased in patients with ANCA disease. These altered T cells are more difficult to control and are producing pro-inflammatory cytokines, which may exacerbate disease.

McGregor JG, Hogan SL, Hu Y, Jennette CE, Falk RJ, Nachman PH. Glucocorticoids and relapse and infection rates in anti-neutrophil cytoplasmic antibody disease. Clin J Am Soc Nephrol 2012; 7(2):240-7. PMCID:PMC3280023

Researchers used clinical data to study steroid use and its association with infections in patients with ANCA-associated vasculitis. They found that treatment with glucocorticoid (steroid) therapy for six months or more is associated with a higher risk of infections. Using glucocorticoids after six months was not shown to decrease the risk of relapse. This research may help clinicians think more about when and for how long to prescribe glucocorticoids.

Lionaki S, Derebail VK, Hogan SL, Barbour S, Lee T, Hladunewich M, Greenwald A, Hu Y, Jennette CE, Jennette JC, Falk RJ, Cattran DC, Nachman PH, Reich HN. Venous thromboembolism in patients with membranous nephropathy. Clin J Am Soc Neph, Jan 2012; 7(1):43–51. PMCID: PMC3265338

Investigators used clinical data to study the frequency of venous thromboembolic events (blood clots) in patients with membranous nephrology (MN). In their study, about 7% of patients with MN had a venous thromboembolic event. A major risk factor for having an event was a serumalbumin measure of <2.8 g/dl, which is associated with worse nephrotic syndrome.

Poulton CJ, Nachman PH, Hu Y, McGregor JG, Jennette JC, Falk RJ, Hogan SL. Pathways to renal biopsy and diagnosis among patients with ANCA small-vessel vasculitis. Clin Exp Rheumatol. 2013 Jan 23-Feb Suppl.75: S32-S37.

Researchers used a telephone survey to learn more about how patients negotiated the health care system between the onset of their first symptoms of vasculitis until they received a kidney biopsy diagnosis of the disease. They found that many ANCA vasculitis patients experience a delay in diagnosis, often due presenting with non-kidney symptoms like a rash, sinusitis, or lung problems. Better algorithms are needed to identify non-kidney manifestations of disease and expedite the diagnostic process, especially for vasculitic involvement of the kidneys.

FAQ: New Health Care Marketplaces

By Caroline J. Poulton, MSW

As a result of health reform, starting in 2014 all individuals will be required to have health insurance . Health Care Marketplaces (also know as "exchanges") are being created to help consumers navigate the different plans that will be available. Below are some frequently asked questions about the new marketplaces.

I have Medicare and/or Medicaid. Do I need to do anything?

If you or your child receive Medicare and/or Medicaid you are already covered and the marketplaces do not effect you.

If I have individual insurance or insurance through my employer, can I get coverage through the new marketplace?

Yes, if you have individual or employer insurance you can use the marketplace to replace what you currently have.

I do not currently have insurance. How does the marketplace work for me?

You can use the marketplace to purchase insurance. When you apply through your state marketplace, the system will use your income and other indicators to determine whether you are eligible for public programs like Medicaid or if you are eligible for subsidized health care.

Does every state have its own marketplace?

No. Seventeen states will run their own marketplaces. Seven states will run a marketplace together with the federal government and the remaining states will have marketplaces run entirely by the federal government. To find out the status of your state, visit www.healthcare.gov.

What if I have a pre-existing condition?

Starting in 2014, health insurance plans cannot refuse to cover you or charge you more if you have a pre-existing condition. The only exception are "grandfathered" individual health places—the kind you buy yourself, not from your employer. If you have one of these plans you can switch to a new marketplace plan during enrollment.

When is enrollment?

Open enrollment started October 1, 2013 and ends March 31,2014. Coverage starts as early as January 1, 2014. You can enroll outside of the enrollment period if you have a qualifying life event (move to a new state, change in income, change in family size). Visit www.healthcare.gov to enroll or to be directed to your state enrollment site.

What kinds of plans will be offered in the marketplace?

Plans will vary based on which insurance companies are selling in your state, but all plans must have what are called "Essential Health Benefits". These benefits will include outpatient and hospital care, prescription drugs, preventive services, emergency services, maternity care, rehab services, mental health, and substance abuse services. Insurance companies have to offer plans in four levels: bronze, silver, gold, and platinum. Cost-sharing will vary based on which plan to choose (for example, a bronze plan will have a lower premium but may have higher deductibles and co-pays).

What will happen if I don't sign up?

If you are eligible for insurance through the marketplace but decide not to sign up, you will have to pay $95 per adult and $47.50 per child (up to $285 for a family) OR 1% of your family income, whichever is greater. The penalty will be deducted from your tax return.

Where do I go for more information? You can visit www.healthcare.gov or call 1-800-318-2596.

UPCOMING PATIENT MEETINGS/SUPPORT GROUPS

North Carolina/Raleigh VF Chapter Meeting
Date: Saturday, December 7, 2013
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:

* **Nutrition and Complementary Medicine in Vasculitis**
  Speaker: Dr. Julie McGregor, Assistant Professor of Medicine, UNC-Chapel Hill. Dr. McGregor is a physician/scientist in the UNC Kidney Center who treats vasculitis patients and conducts clinical and translational research in vasculitis.
* **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/

If you are not close to NC, visit www.vasculitisfoundation.org to find a support group near you.

NephCure Walks

The NephCure Walk is NephCure's walking fundraiser designed to raise vital dollars to further our mission of saving kidneys, saving lives. More than a fundraiser, The Nephcure Walk provides support for those lives that have been touched by Nephrotic Syndrome and FSGS while raising awareness in our communities. Come on out and meet other patient famililes

Upcoming Walks in the Southeastern US:

⇒ Charleston, SC: November 3rd, 2013
⇒ Aiken, SC: November 9th, 2013
⇒ Jackson, MS: November 16th, 2013

Register to walk or make a donation at www.thenephcurewalk.org.
If you'd like to plan a walk in your community, send an email to walk@nephcure.org or call 1-866-637-4287 ext.4.

To learn more about NephCure, visit www.nephcure.org for more resources and a calendar of events.

NEW: RITAZAREM: AN INTERNATIONAL, OPEN LABEL, RANDOMIZED CONTROLLED TRIAL COMPARING RITUXIMAB WITH AZATHIOPRINE AS MAINTENANCE THERAPY IN RELAPSING **ANCA-ASSOCIATED VASCULITIS**

Principal Investigator: Patrick Nachman, MD
Sponsors: University of Pennsylvania, National Institutes of Health, and Roche/Genentech
Status: Enrolling

Description: The purpose of the study is to compare the use of rituximab with the use of azathioprine in the prevention of disease flare in ANCA-associated vasculitis (AAV) patients with relapsing disease . 160 participants worldwide will be randomized into two groups. Patients will be recruited at the time of relapse. All will start by receiving 4 doses of rituximab and glucocorticoids (steroids). Patients that achieve disease control (no symptoms of vasculitis and a daily prednisone dose of ≤ 10mg) by month 4 will then be randomly assigned to one of two groups to either 1) receive more rituximab and steroids or 2) receive azathioprine. Patients in the Rituximab maintenance group will then get five more rituximab doses at months 4, 8, 12, 16 and 20 and glucocorticoids. Patients in the azathioprine group will receive azathioprine for 23 months and glucocorticoids for 16 months.

Eligibility Criteria:

Subjects must meet all of the following criteria to be eligible for enrolment:

1. Written informed consent (18 years and above)
2. A diagnosis of AAV (granulomatosis with polyangiitis (Wegener's) or microscopic polyangiitis), according to the definitions of the Chapel Hill Consensus Conference
3. Current or historical ANCA positivity either by ELISA or immunofluorescence.
4. Disease relapse
5. No previous recent therapy with a biological B cell depleting agent (such as rituximab or belimumab)

For more information, please contact:

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The Renal Support Network's KidneyTalk is an online bi-weekly, half-hour radio talk show than launched in June of 2006.

This novel undertaking features RSN Founder & President Lori Hartwell. Periodically Stephen Furst, an accomplished television and movie actor/producer/director and transplant recipient is her co-host.

With Lori Hartwell's 44 years as a renal disease survivor and Stephen Furst's entertainment credentials, KidneyTalk provides the audience with practical advice on how to live a full and productive life despite CKD.

Each show is available online 24 hours a day or can be downloaded free any time from the iTunes store using your iTunes App, and includes at least one guest interview with someone who is well-qualified to comment on the topic at hand and share their stories of health, happiness or hope. Listen in at www.rsnhope.org!

NEW: A 2-YEAR STUDY OF EFFICACY AND SAFETY OF INTRAVENOUS BELIMUMAB VERSUS PLACEBO IN SUBJECTS WITH **IDIOPATHIC MEMBRANOUS NEPHROPATHY (IMN).**

Principal Investigator: Patrick Nachman, MD
Sponsors: GlaxoSmithKline
Status: Enrolling

Description: The purpose of the study is to test if belimumab and supportive therapy is better than supportive therapy alone in the treatment of membranous nephropathy. Supportive therapy includes Angiotensin-converting enzyme inhibitors (ACEi), and/or Angiotensin receptor blockers (ARB).
Supportive therapy may include:

- Statins
- Diuretics
- Dietary salt restriction

94 patients will be enrolled 5 will be enrolled at UNC) and will be placed either in the group receiving an infusion of belimumab or in the group receiving an infusion of placebo (an infusion containing no drug). Participation in the study lasts 28 months. The infusions will be done on days 0, 14, 28; then every 4 weeks through and including week 100, for a total of 27 doses. Patients losing a large amount of protein in the urine might need to come every 2 weeks to compensate for the loss of belimumab in the urine.

Main eligibility criteria: 18 to 75 years of age, with a new diagnosis of membranous nephropathy.

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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.

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

NEW: ASSESSMENT OF THE EFFICACY OF LIPID-LOWERING AGENTS TO LIMIT LIPID OXIDATION AND ACTIVATION OF THE CLOTTING SYSTEM IN PATIENTS WITH **NEPHROTIC SYNDROME**: A PILOT RESEARCH STUDY.

Principal Investigator: Vimal Derebail, MD MPH
Sponsors: NephCure Foundation
Status: Enrolling

Description: A prospective interventional pilot study to determine whether administration of pravastatin can attenuate coagulation activation in nephrotic syndrome (NS) by reducing oxidized low-density lipoprotein (oxLDL).

We are enrolling patients with biopsy proven nephrotic syndrome (minimal change disease, membranous nephropathy, or focal segmental glomerulosclerosis). Following screening, subjects will make 3 visits over a 6 week period (0 wk = baseline, 3 weeks and 6 weeks). Laboratory and safety data will be collected at the baseline visit and again at 3 weeks and 6 weeks. All patients will receive 20mg of pravastatin beginning at the baseline visit. Pravastatin will be increased up to 40mg after 3 weeks of treatment. Each visit will last about 45 minutes. At 12 weeks, all patients will receive a follow-up phone call.

Total number of patients: 10; Length of participation: 12 weeks

Inclusion Criteria :

- Patients, ages 18-70, with a biopsy-proven diagnosis of Membranous Nephropathy (MN), Focal Segmental Glomerulosclerosis (FSGS), or Minimal Change Disease (MCD).
- Protein in the urine (>=3.0 gm/day by 24hr urine collection or spot urine protein-creatinine ratio >=2.0).

  LDL ≥ 150 mg/dl.

Main Exclusion Criteria :

Inability or unwillingness to comply with the study protocol and follow-up visits.

For women: Breastfeeding, pregnant or planning to become pregnant or unwilling to use contraceptive measures during the study.

Prior intolerance of statins

Any other contraindication to statin therapy.

Unable to provide written consent.

For more information please contact:

Dr. Vimal Derebail, vimal_derebail@med.unc.edu ; (919) 966-2561 x225

Anne Froment, study coordinator anne_froment@med.unc.edu; (919) 966-2561 x247

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

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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 intervals (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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VENUS THROMBOSIS IN **ANCA VASCULITIS**

Principal Investigator: Patrick Nachman, MD
Funding Source : National Institutes of Health
Status: Enrolling *(Thank you to the 36 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.

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

Principal Investigator: Patrick Nachman, MD
Sponsors: Food and Drug Administration
Status: Enrolling *(Thank you to our three participants already enrolled!)*

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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Recipe Box: Savory Green Beans

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

Recipe submitted by DaVita dietitian Heather.
Portions: 6 **Serving Size**: 1/2 cup

Ingredients

- 1 pound frozen French style green beans
- 1 tablespoon oil
- 1/2 cup onion
- 1 garlic clove
- 2 teaspoons dried dill weed
- 1 tablespoon lemon juice
- 1 teaspoon Worcestershire sauce
- 1/3 cup plain bread crumbs
- 2 tablespoons unsalted butter

Preparation

1. Preheat oven to 400° F.
2. Chop onion and mince garlic.
3. Cook green beans in microwave according to package directions.
4. In a medium skillet, heat oil and sauté onion with garlic, until onion is translucent.
5. Add dill weed, lemon juice and Worcestershire sauce and stir to mix.
6. Add green beans and toss. Place in a casserole dish .
7. Melt butter and mix with bread crumbs. Sprinkle over green bean mixture and bake for 5 to 10 minutes to brown.

Nutrients per serving

Calories 110
Protein 2 g
Carbohydrates 11 g
Fat 7 g
Cholesterol 11 mg
Sodium 53 mg
Potassium 167 mg
Phosphorus 35 mg
Calcium 60 mg
Fiber 2.3 g

Renal & renal diabetic food choices: 1 vegetable, 1 fat, 1/2 starch
Carbohydrate Choices: 1

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For more kidney disease information,
internet links, and printable copies of this newsletter, check out
our website: **www.unckidneycenter.org**

Patient Education Podcasts
UNC Kidney Center

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!

Glomerular Disease Collaborative Network

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