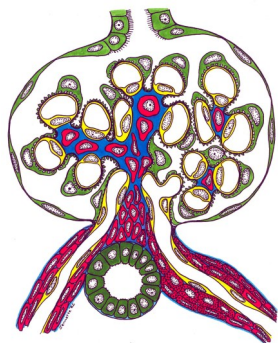


# KIDNEY CARE



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

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## JALEKA'S STORY: THINKING POSITIVE AND LOOKING TOWARDS THE FUTURE

*The following contains excerpts from essays written by a young adult living with lupus, an autoimmune disorder that can involve the kidneys.*

My name is Jaleka and I am a middle school student. A lot of people look at me different. They wonder what's wrong with me. In 2008, I was diagnosed with mixed connective disease. Then in 2010, I was diagnosed with lupus. I am currently helping doctors at UNC Chapel Hill and Duke study lupus. What is lupus? Lupus is an autoimmune disease that can attack any part of your body. It attacked my hair, face, hands, feet, legs, liver, and kidneys. Some days I was not able to walk. I had high fevers and low levels of Vitamin D. Ask your parents to get you checked for lupus and please get your Vitamin D levels checked. I have a rash on my face called a "butterfly rash". The medicine that they have me on is a steroid, which causes me to gain weight. I eat all the time. I have been picked on by children but I keep the faith. I have been asked by children and adults wondering if I was pregnant. The answer is no!



We must learn to think positive when we see situations and not focus on the negative. The more you learn about this illness and its symptoms the better of you will be. I encourage you to take what I have talked about to heart. Don't take life for granted and live every day to the fullest. There is no cure for lupus but "God is able". He has brought me through all my situations. I never complain. I keep a smile on my face. I am happy all the time.

I can play sometimes but I get tired easily. When the sun is bright I have to wear shades and sunblock. My mom helps take care of me. She is always there for me making sure I go to appointments and take all my medicine. I have been strong through it all by God's grace. I have also been strong for my mom.

I never let what I was going through stop me from getting where I need to be. I missed many months of school because I was sick, but I kept pressing my way. I was homeschooled for months and maintained good grades. I love school. I want to be an inspiration to someone else. School is my passion.

My first goal for life is to graduate from high school and go to college. I would like to become a school teacher. I would like to be a teacher because I want to educate others. Teaching can help you reach goals in life. The more you know the more you grow. When I become a teacher I will teach the children good study habits, communication skills, and how to deal with life's challenges. My teachers have been my mentors and they aided me when I didn't understand some of my work. They also taught me skills I need to face this challenge.

*Continued on page 2....*

*Jaleka's story continued..*

The community services I am involved in have also helped me. I am a bowler and have been bowling since I was 3 years old. I have received scholarships for bowling well in competitions. The scholarships will help pay for college. Bowling teaches you discipline and team work.

I have also been involved with public speaking. I received a certificate for participating in the Dr. Martin Luther King oratorical contest. I also entered the County Soil and Water speaking contest and won first place. I went to the district competition and received an honorable mention. I have been speaking to the area church's youth department about lupus. I love to do public speaking. Speaking out makes you stronger as a person. It also helps you prepare for college.

I am also a member of the Delta Academy ladybugs. As a ladybug I have learned new math and science technology. I enjoy meeting other young ladies like myself. My self-esteem is very high. I have also learned to be confident in myself. I am an active youth participant in church. I sing in the youth choir and I am on the youth usher ministry. I also participate in church wide activities. My religion gives me strength.

Never doubt yourself when reaching your goals. I will never give up on my life's goals. I will and can defeat all challenges. My dreams will be a reality. I challenge every one of you to find your passion. Whatever it may be. I found mine. Will you?

## A RENAL ROOKIE'S COOKING CHALLENGE

*Prepared by Ed Robinson*

Reprinted with permission from Renal Support Network RSNhope.org

When I was asked to prepare a renal (kidney) friendly meal for a friend on dialysis, I thought, "Sure, no problem. I cook healthy all the time. I just have to make sure to provide plenty of whole grain breads, wild rice, fruits, and plenty of water. Easy, right?" I couldn't have been more wrong.

The Renal Diet is so tricky because it is so counter-intuitive. Every other restrictive diet I can think of is just an extreme version of regular healthy eating: low carb, low sugar, low sodium, low mercury, and high in nutrients. I learned that cooking properly for a person with kidney disease, I have to throw these pre-conceived ideas out the window. While it's easy to learn that someone on dialysis needs to have very minimal fluids, what is less easy is keeping meals low in phosphorus, potassium and sodium while providing high protein. It is especially difficult when many food labels do not include either phosphorus or potassium.

All is not lost, however, because once you get used to the renal diet, there are plenty of delicious foods left to include. As a result, I created a few recipes that are tasty and meet the suggested guidelines. The Imperial Indian Chicken (recipe on page 3) uses large bone-in chicken breasts for plenty of protein seasoned with a flavorful salt-free dry rub. The glaze also has a good amount of lemon juice, which is another great way to add flavor without sodium. It is served with white rice, which is lower in phosphorus than either brown or wild rice.

And of course, everyone has a bit of a sweet tooth, but with chocolate and peanut butter being high in phosphorus and potassium, how do I prepare a cookie that is tasty without using these key ingredients? The answer, I found, is butterscotch and/or caramel. Butterscotch Cookies made with cream of wheat makes the perfect cookie for the renal diet. And, for an even more decadent, but still renal-friendly treat, I made a caramel-filled butterscotch chip cookie (recipe on page 3).

While it was a challenge to learn how to cook renal-friendly, it was mostly because of the large learning curve. Once I discovered what foods and seasonings I had to work with, there was no reason I couldn't create great tasting meals for my friend.



*Recipes on next page...*

*Renal Rookie Continued....*

### Imperial Indian Chicken with White Rice

#### INGREDIENTS

- 1 Jar Trader Joe's Mango Ginger Chutney  
(or another brand without High Fructose Corn Syrup)
- 2 T unsalted butter or butter substitute
- 1 T Lemon juice
- 2 Bone-In split chicken breasts
- 1 T Olive oil
- 1/2 Cup Green Onions, chopped,  
including the green stems (optional)
- 1 cup white rice

#### For the Dry Rub:

- 1 tsp .Curry powder
- 1/2 tsp .Paprika
- 1/2 tsp. Onion powder
- 1/2 tsp. Garlic powder
- 1/2 tsp. Ground ginger
- 1/2 tsp. Cumin

#### DIRECTIONS

- Preheat the oven to 450 degrees.
- Prepare the Dry Rub by combining all the dry ingredients.
- Rub the Chicken Breasts with the Dry Rub and Olive Oil, making sure to get the rub underneath the skin of the chicken breast.
- Cook 1 cup of White Rice in a rice cooker. After the rice is done cooking, add 1 T of chutney and half of the chopped green onions.
- Place the chicken in a roasting pan and roast at 450 degrees for 25 minutes.
- Meanwhile, prepare the glaze by melting the butter into the remaining chutney in a small saucepan. After the butter has melted and the chutney has heated through (about 5 minutes,) add the lemon juice and remove from the flame.
- After 25 minutes, Spoon half of the prepared glaze onto the chicken breasts. Return to the oven and roast for 5 more minutes or until an instant read thermometer reads an internal temperature of 160 degrees.
- Remove the Chicken from the oven and spoon remaining glaze over the chicken.
- Serve the Chicken over the rice, passing any pan juices as extra sauce.

### Gooey Caramel-Filled Butterscotch Cookies

- Preheat oven to 350 degrees. Cream the butter with the sugars using an electric mixer on medium speed until fluffy (approximately 30 seconds).
- Beat in the egg and the vanilla extract for another 30 seconds.
- In a mixing bowl, sift together the dry ingredients and beat into the butter mixture at low speed for about 15 seconds. Stir in the butterscotch chips.
- Using a 1 Tablespoon ice cream scoop, drop cookie dough onto a greased cookie sheet or a cookie sheet lined with parchment paper about 3 inches apart. Place one caramel square in the center and top with another tablespoon of dough.
- Roll the dough in your hands so they are a nice even ball.
- Bake for about 12-20 minutes or until nicely browned around the edges. The cookies will remain fairly thick and not spread out like other kinds of cookies.
- Let the cookies cool completely on the cookie sheet. Some of the caramel may have sunk to the bottom, so to avoid breaking the cookies, this is an important step.
- To fully enjoy cookies over the next few days, microwave one or two at a time for 10 seconds.

#### INGREDIENTS

- 1/2 cup (1 stick) unsalted margarine
- 1 cup light brown sugar
- 3 tablespoons granulated sugar
- 3 Tbsp of Egg alternative (or one large egg)
- 2 teaspoons vanilla extract
- 1-3/4 cups all purpose flour
- 1/2 teaspoon baking powder
- 1/2 teaspoon baking soda
- 1-1/2 cups butterscotch morsels
- 1/2 bag of caramel cubes

## KIDNEY TRANSPLANT EVALUATION AT UNC: WHAT IS INVOLVED?

By Jenny Hawley, MSN, Family Nurse Practitioner, UNC Kidney Center

Your kidney doctor (nephrologist) may have suggested a kidney transplant as a possible treatment option for you. If so, what is involved in this process? What can you expect if you have been referred by your kidney doctor for transplant evaluation at UNC? This article will address the kidney transplant evaluation process at UNC.

What if you have been referred for evaluation at a transplant center other than UNC? You can expect the process to be similar with minor differences. It is best to check with your transplant center for more information about their process. If you would like more general information on pre-transplant evaluation, visit [www.transplantliving.org/beforethetransplant](http://www.transplantliving.org/beforethetransplant).

First of all, you will be contacted by one of the UNC Kidney Transplant Team staff to schedule you to attend a Kidney Transplant Orientation class that is held regularly at UNC Hospitals in Chapel Hill, NC. If you live in or near Wilmington, Asheville, Rocky Mount or Wilson, NC and see a kidney doctor there, you may be able to go to a Kidney Transplant Orientation class and see a transplant nephrologist at one of our outreach transplant clinics that travel to these locations.

After the class, you will be assigned to a special nurse who will be your pre-transplant coordinator to help you with this process, to schedule your appointments and evaluations recommended by our doctors, and to answer your questions. You will need to keep your nurse coordinator updated if your address or phone number(s) change or if you have changes in your medical condition. They will serve as your "point person" during the entire pre-transplant evaluation process.

You will need to come to UNC Hospitals in Chapel Hill for clinic visits for your evaluation and for several tests and laboratory studies specific for your pre-transplant work-up. You will meet your nurse coordinator at this time, see one of our kidney transplant doctors and transplant surgeons, and meet with our social worker. After these clinic visits, a transplant committee will review your case and inform you if you are a good candidate for a kidney transplant.

The medical evaluation is very thorough to be sure you are healthy for this surgery and can take several months to complete. You will not be listed on the kidney transplant waiting list until the entire evaluation is completed and you have been approved for a kidney transplant. The evaluation usually includes the following:

- Special labs, heart activity scan (EKG), x-ray, renal (kidney) ultrasound, cardiac (heart) echo.
- Evaluation with one of our Nephrologists and Transplant Surgeons.
- Social worker visit to assess support system.
- Visit with a specialist (such as Cardiology (heart) or Urology (urinary tract)) based on your medical history.
- Meeting with a financial coordinator to discuss financial issues related to transplant and post-transplant medications.
- Health maintenance screening, including up-to-date mammogram, Pap smear, colonoscopy and PSA (prostate cancer screening).

Our Kidney Transplant Team is a group of dedicated and caring health professionals who are committed to providing the best care for our patients. To learn more about us and our transplant evaluation process, please visit the UNC Center for Transplant Care web site at [www.unckidneytransplant.org](http://www.unckidneytransplant.org) or call us at (888) 263-5293.

## HOPEline

If you have chronic kidney disease  
and don't know what to expect call

English

1-800-579-1970

Support from someone  
who's been there.

Monday-Friday 10am-8pm (PST)



Si tiene enfermedad renal crónica  
y no sabe que le espera

Español

1-800-780-4238

alguien que ya estuvo ahí  
le ofrece su apoyo.

Lunes-Viernes 10am-8pm (hora del Pacífico)

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## NEWS FROM THE HILL: CURRENT BILLS AFFECTING KIDNEY PATIENTS

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### **S 1454: Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2011**

Currently, transplant recipients who are covered by Medicare because of their kidney failure only (not age or disability status) receive coverage for 36 months (3 years) after transplant and then lose their Medicare coverage. This bill would make it possible for transplant patients under 65 who are not classified as disabled to keep their Medicare Part B benefits throughout the life of the transplant. Under this legislation, a kidney transplant recipient would have access to immunosuppressive drugs under Medicare Part B while still paying the Part B deductible and premiums. Medicare would be the secondary payer if the patient has private insurance.

Status: In Senate Committee, not yet introduced in the House of Representatives

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### **HR 2755: Share Your Spare Act of 2011**

Although Medicare covers the medical expenses of most living donors for the donor surgery in evaluation, some potential donors may decide not to donate due to the cost of non-medical expenses related to transplantation, like time away from work, travel, childcare, and lodging. Under this legislation, taxpayers who donate an organ can apply for a federal tax credit of up to \$10,000 to reimburse non-medical expenses and lost wages related to the organ donation.

Status: In House Committee, not yet introduced in the Senate

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### **HR 5844: Fairness in Medigap Options Act of 2010**

Amends title XVIII of the Social Security Act to provide all Medicare beneficiaries with the right to guaranteed issue of a Medicare supplemental policy (Medigap) and annual open change-in-enrollment periods. Currently, federal law does not allow Medicare beneficiaries under the age of 65 (alot of whom are ESRD patients) to purchase Medigap Coverage. Thirty-one states have passed their own legislation to allow coverage.

Status: In House Committee, not yet introduced in the Senate

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*Want to contact your State Representatives and urge support for the bills listed?*

**On the web:**

<http://www.house.gov>

<http://www.senate.gov>

**By Phone:**

1(800) 333-4636

Use these resources to find out who represents you and how to contact them. If you need help locating your representative, leave a message on the GDCN patient line with your name, address, and telephone number and Caroline will let you know who they are :  
1-877-462-9371

***The Renal Support Network's Wellness & Education Kidney Advocacy Network is an excellent resource for kidney patients who want to advocate on a national level. Please visit [www.rsnhope.org](http://www.rsnhope.org) for more information.***



For more kidney disease information,  
internet links, podcasts, and printable copies of  
this newsletter, check out  
our website:  
[www.unckidneycenter.org](http://www.unckidneycenter.org)

## COMPLEMENTARY & ALTERNATIVE MEDICINE: DO YOU USE IT?

By Libby Berg, Research Specialist

The 2007 National Health Interview Survey (NHIS) reports 38 percent of United States adults 18 years and older use some form of complementary and alternative medicines (CAM). The use of CAM has been growing in the United States. As the use of CAM increases, researchers have become more interested in studying its effects on the body. Healthy or not, there are many reasons for trying CAM. **Have you ever contemplated using CAM?** Before answering, let's define CAM as well as provide some common examples.

### **CAM Definition**

Complementary and alternative medicine is a broad field with a definition that is still changing. The current definition, adapted from the National Institutes of Health, helps to provide a general framework:

*The term "complementary and alternative medicine" refers to a group of medical and health care systems, practices, and products that are not generally considered part of conventional medicine. Conventional medicine (also called Western or allopathic medicine) is medicine practiced by medical doctors, doctors of osteopathy and allied health professionals, such as physical therapists, psychologists, and registered nurses. Conventional medicine and CAM can overlap.*

CAM treatments vary depending on health status, population group, available resources and treatment purpose. Individuals have different reasons for using CAM. Most often, CAM is used to relieve pain or promote general health. The following examples are common forms of CAM:

Acupuncture	Hypnosis	Reflexology
Chinese medicine	Massage therapy	Reiki
Chiropractic services	Meditation	Relaxation techniques
Exercise promotion	Minerals	Spiritual healing
Guided imagery	Naturopathy	Tai Chi
Herbs	Nutritional supplements	Vitamins
Homeopathic remedies	Qigong	Yoga

See any familiar CAM examples? Below describes in greater detail a few CAM examples:

- *Acupuncture* is the stimulation of specific points on the body by a variety of techniques, including the insertion of thin metal needles through the skin. Acupuncture intends to remove blockages in the flow of qi (a person's vitality or "life force") and restore and maintain health.
- *Homeopathy's* basic principle is "let like be cured by like." This practice seeks to stimulate the body's ability to heal itself by giving small doses of a highly diluted substance that in larger doses would produce illness or symptoms.
- *Reiki* is a therapy in which practitioners seek to transmit a universal energy to a person, either from a distance or by placing their hands on or near that person. The goal is to heal the spirit, which will then heal the body.

From acupuncture to yoga, to herbs and vitamins, for some individuals, CAM can provide a powerful healing tool. Figuring out which type of CAM is most beneficial to patients is the central aim of many research studies.

*Continued on page 7...*



**Don't forget to check out our glomerular disease patient education podcasts at :**

**<http://www.unckidneycenter.org/podcast.html>**

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

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## VENOUS THROMBOSIS IN ANCA VASCULITIS

**Principal Investigator:** Patrick Nachman, MD

**Funding Source :** National Institutes of Health

**Status:** Enrolling

**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  $\geq 18$
- Diagnosis of active ANCA disease
- Active disease as indicated by a BVAS of  $\geq 5$  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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*Complementary & Alternative Medicine continued...*

### **CAM Usage in Various Diseases**

Complementary and alternative medicine is frequently used by a variety of patients diagnosed with different diseases. Patient groups that use CAM include cancer, arthritis, chronic back pain, gastrointestinal (stomach) ailment, chronic fatigue and lupus (an autoimmune disease). For most patient groups, the reason for using CAM is to alleviate symptoms related to the disease process or to assist in symptoms related to treatment side effects.

Discussing possible complementary and alternative medicines with your physician before using them is important- especially if you are pregnant, nursing, taking other medications or have chronic health problems.

### **CAM in Small Vessel Vasculitis**

Researchers at the UNC Kidney Center are conducting a descriptive study to help understand if patients with small vessel vasculitis use CAM in conjunction with their standard care. Study objectives include asking patients which types of CAM they use (if any), how they learned about it, and if they discuss CAM with their physicians.

*\*It is important to discuss possible complementary and alternative medicines with your physician before using - especially if you are pregnant, nursing, taking other medications or have chronic health problems.\**

Thanks to all who have participated! For more information and/or to participate, please contact Libby Berg at [elisabeth\\_berg@med.unc.edu](mailto:elisabeth_berg@med.unc.edu) or leave a message on our toll-free line: 1-866-462-9371.

## 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

**Description:** Multi-centre, 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 polyangiitis (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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## CYCLOPHOSPHAMIDE-RELATED UROTHELIAL TUMOR EVALUATION

**Principal Investigator:** Patrick Nachman, MD

**Sponsor :** none

**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 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:

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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 2011, a total of 110 volunteers from all sites have become a part of the study, with 13 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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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 soon

**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/m<sup>2</sup>
- 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:

Anne Froment  
(919) 966-2561 ext 247  
[anne\\_froment@med.unc.edu](mailto:anne_froment@med.unc.edu)

Sandy Grubbs  
(919) 966-2561 ext 245  
[Sandra\\_grubbs@med.unc.edu](mailto:Sandra_grubbs@med.unc.edu)

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## A MULTICENTER, RANDOMIZED, PROSPECTIVE, OPEN-LABEL TRIAL OF RITUXIMAB IN THE TREATMENT OF PROGRESSIVE IGA NEPHROPATHY

**Principal Investigator:** Patrick Nachman, MD

**Sponsor :** Genentech

**Status:** Enrolling

**Description:** The purpose of this study is to compare the ability of Rituximab to standard therapy (tight blood pressure control and fish oil) in lowering protein in the urine in patients with IgA nephropathy, and to examine the side effects occurring with Rituximab. Approximately 50 patients (5 for UNC Kidney Center) will be randomized to Rituximab in addition to standard therapy vs. standard therapy alone in an open-label multicenter controlled trial. Patients randomized to the Rituximab group will receive a total of 4 doses on days #1; 15; 168 and 182. Standard therapy will consist of combination of blood pressure medications (angiotensin converting enzymes inhibitors (ACEi) and Angiotensin Receptor Blockers (ARBs) to achieve a blood pressure goal of 125/75 (MAP 90 mm Hg) and Omega-3 Fatty Acid Fish Oil Supplements, 3.6 gm EPA/day. Patients will be followed for a total of 12 months.

### Main Inclusion Criteria:

**Note:** All eligible patients will have undergone a renal biopsy compatible with a diagnosis of IgA nephropathy within **24 months** of study entry.

- **Age 18-70**
- Kidney biopsy compatible with a diagnosis of IgA nephropathy within **24 months** of study entry.
- **Kidney Insufficiency:** estimated glomerular filtration rate (GFR) <90mls/min and >30mls/min
- **Well controlled Blood Pressure:** BP <130/80 mmHg. Any patient needing long term hypertensive medications must have BP controlled <130/80 mmHg to be considered eligible.

### Main Exclusion Criteria:

- Known infection with HIV, (patients will be serologically screened prior to study entry).
- Pregnancy (a negative serum or urine pregnancy test will be performed for all women of childbearing potential no later than 7 days prior to treatment) or lactation. Unwilling to take contraception for 2 years.
- Having received > 6 months therapy with oral prednisone or glucocorticoid equivalent.

For more information, please contact:

Anne Froment

(919) 966-2561 ext 247, [anne\\_froment@med.unc.edu](mailto:anne_froment@med.unc.edu)

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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 kind 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, participant 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. *Continued on Page 12...*

## THE ACCESS TRIAL: STUDYING ABATACEPT & CYCLOPHOSPHAMIDE IN PATIENTS WITH LUPUS NEPHRITIS

Lupus nephritis is a kind of kidney inflammation that occurs in patients with systemic lupus erythematosus (SLE). It is caused by the immune system attacking the kidney. It is among the most serious complications of SLE, and left untreated it can cause long term damage to the kidneys or, in some cases, result in kidney failure.

One of the more common treatments for lupus nephritis is the "Euro-lupus" therapy. In this therapy, patients receive three different drugs - cyclophosphamide, azathioprine and prednisone - over the course of several months. However, some patients do not respond to this therapy and many only show some improvement.

In the ACCESS trial for lupus nephritis, an experimental medication known as abatacept will be added to the Euro-lupus therapy to find out if it works better than Euro-lupus therapy alone. Abatacept is a man-made protein that suppresses parts of the immune system that can cause autoimmune disease. While abatacept is experimental for lupus, it has been approved by the FDA to treat rheumatoid arthritis. It is also being studied for use in other autoimmune diseases, like multiple sclerosis and type 1 diabetes.

Participants in the ACCESS trial for lupus nephritis will receive bi-weekly intravenous infusions of cyclophosphamide for 3 months, then will take azathioprine tablets daily for at least 3 months more. Abatacept or a placebo will be administered every 2 weeks at first, then every 4 weeks for at least the first 6 months. Treatment of abatacept or placebo and azathioprine may continue for the remainder of the year. All subjects will take prednisone tablets daily during the whole study.

Because the ACCESS trial is a randomized, controlled study, each participant has a 50-50 chance (like flipping a coin) of receiving abatacept. Others will receive an inactive, placebo form of the drug. Note however, that all participants will receive the Euro-lupus therapy. As a blinded study, neither participants nor study physicians will know to which group a person has been assigned.

All participants will undergo regular physical examinations, medical history and various blood and urine tests. Many of these tests will be repeated throughout the study. Participants will be asked to attend 18 study visits in the first year, and one study visit at the end of the second year.

### Inclusion Criteria:

- Men and women 16 years of age or older
- Diagnosis of lupus and documentation of active lupus nephritis in the 12 months before study entry
- Positive antinuclear antibody test (ANA) at time of study entry

### Exclusion Criteria

- End stage kidney disease
- Use of cyclophosphamide in the last 12 months
- Pregnant or breastfeeding
- History of cancer, active infection, anemia

For more information contact:  
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919-843-6619  
[Brenda\\_meier@med.unc.edu](mailto:Brenda_meier@med.unc.edu)

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Diabetic Kidney Disease Study Continued from page 11...

### 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:

Anne Froment  
(919) 966-2561 ext 247  
[anne\\_froment@med.unc.edu](mailto:anne_froment@med.unc.edu)

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## UPCOMING PATIENT MEETINGS/SUPPORT GROUPS

### North Carolina/Raleigh VF Chapter Meeting

Date: December 3, 2011

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:

\* **Are you an "Expert Patient?"**

Clara Neyhart, Certified Nephrology Nurse Clinician in the UNC Kidney Center, will be talking about being an expert patient and the things expert patients do to manage their care.

\* **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](mailto: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.



- ◇ SHARE your experiences
- ◇ MEET other patient families

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 and support group meetings, also THE NEPHCURE WALK is coming to the following areas soon:

Aiken, SC October 15, 2011

Raleigh, NC November 12, 2011

- ◇ LEARN about opportunities in your area to take action!
  - Specific topics surrounding FSGS and Nephrotic Syndrome
  - How NephCure can serve you as a resource

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](mailto:jcherry@teamnephcure.org)

You can also check us out on the web at [www.nephcure.org](http://www.nephcure.org)

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A Newsletter from the  
Glomerular Disease  
Collaborative Network

Burnett Womack, CB#7155  
Chapel Hill, NC 27599-7155

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



**UNC**  
KIDNEY CENTER

[www.unckidneycenter.org](http://www.unckidneycenter.org)

**Remember to T.E.S.T Your Family Members**



- T** Teach them that kidney disease runs in families.
- E** Encourage them to get tested for kidney disease.
- S** Support their efforts to control their diabetes and high blood pressure.
- T** Tell them where they can find more information :  
[www.unckidneycenter.org](http://www.unckidneycenter.org) (1-866-256-2930) or  
[www.nkdep.nih.gov](http://www.nkdep.nih.gov) (1-866-454-3639)