

FSGS

CLINICAL TRIAL

OCTOBER 2006
NEWSLETTER

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RESTRUCTURING THE CORES

We have officially switched to 3 Core Centers, now known as A, B, and C to consolidate resources. The trial support for each participating site will be a nationwide effort. The FSGS trial Coordinators and Investigators are here to serve. See Contact information below, and on the website under "Participating Sites".

INVESTIGATOR MEETING

Come to lunch at the ASN! During ASN we will be having an investigator meeting for the trial. It will be held in the Santa Rosa room at the Marriot hotel at 12:15pm on Thursday November 16th. San Diego will kick-start us into the next 16 months of higher recruitment! FSGS-CT Study poster at the NIH Clinical Trials area.

COORDINATOR MEETING

There will be a study coordinator's meeting February 2007 in Orlando. Organized for Coordinators by Coordinators means we'll get a lot done and have fun doing it. Investigators are welcome, especially those without coordinators themselves.

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CORE A

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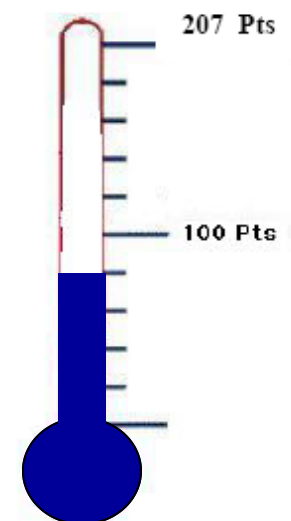
CORE B

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CORE C

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OUR GOAL: 207
CURRENT STATUS: 78



TIP OF THE WEEK

After a few urine incidents, we've come up with a good solution to those pesky two urine at screening and weeks 26, and 52. We've found that having a patient bring in 3 urine samples cuts down on the hassle of having to collect extra urines to make up for samples that skew the Up/c averages.

NEW LOGO AND NEW WEBSITE

We have a new FSGS Clinical Trial logo and an updated website. One of the features of the new website will be rotating images of the study sites, core centers, and patient's stories. If you have a patient story or photos of your study team, please contact Michelle Mitchell at:

michelle_mitchell@med.unc.edu

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REPOSITORY CONSENTING

"If it's going to help someone else, then sure. No problem". This is the type of response I've gotten when I consent patients for repositories. Sure, it's extra blood to give—but blood draws happen everyday. We worry that we're asking too much of our patients, but keep this in mind:

- Repositories are just as important as the trial itself. Being able to expand the study to basic science studies may help focus therapy in the future
- Patients want to find a cure more than anyone, so of course they're interested!
- You can space out consenting for repositories until week 0, and space out DNA repository collections for minimal blood draw visits.

STOPPING CSA AT WK 52

According to protocol, the study medications cyclosporine, MMF, and dexamethasone should be completely stopped at the 52 week visit. This design was implemented to enable determination of the durable response rate to a 1-year course of therapy. The protocol does not detail any taper regimen and instead requires complete cessation of the drug.

"If it's going to help someone else, then sure. No problem."

-FSGS Patient 212013 when asked about consenting for Repositories

THE IMPORTANCE OF HYPERTENSION CONTROL

A recent review of patient blood pressure (BP) values at study entry unexpectedly showed that 35% of study patients enrolled at baseline had uncontrolled hypertension. Concerns have been raised that severe hypertension may significantly impact outcomes, thus adding a covariate that could complicate assessment of treatment effect.

During the October Clinical Management Committee (CMC) meeting chaired by Debbie Gipson M.D., the committee concluded that patients will not be randomized until their BPs are normalized. Study investigators and research coordinators entering a patient into the study will be notified about the high BP and will be asked about planned treatment.

Interestingly, blood pressures problems have not been confined to the enrollment period. 58% of current study patients have had measurements of blood pressure greater than the target range. In response to this problem, the CMC will review all submitted BPs during their monthly meetings and will notify study investigators and research coordinators when one of their patients is hypertensive. All elevated blood pressures will be handled as an adverse event.

By addressing patient hypertension, the potential for useful FSGS study conclusions will be enhanced.