Featured Spring Research

Featured Industry Sponsored Study:

Zemplar Protocol (Part I—Inpatient)

Purpose: To determine the safety, tolerability, and pharmacokinetics of a single dose of 3 mcg paricalcitol capsules in pediatric subjects with moderate to severe chronic kidney disease (CKD Stages 3 and 4).

Inclusion:
1. Patient is male or female from 10 to 16 years of age
2. Subject has CKD Stage 3 or 4 as determined by eGFR (15 to 59 mL/min/1.73 m²) at Screening.
3. Subject has 25-hydroxyvitamin D levels ≥ 30 ng/mL at Screening

Recruitment Timeline: Ongoing

Featured Registry Study:

KidCOM Study

Purpose: This study will examine atypical hemolytic uremic syndrome (aHUS) and membranoproliferative glomerulonephritis (MPGN) (all subtypes) as specific examples of complement-mediated renal diseases in order to extend our understanding of the underlying pathophysiology, and to develop specific treatment strategies.

Inclusion: Pediatric and adult patients who have been diagnosed (by biopsy result or fulfilling clinical criteria) with aHUS, or MPGN (all subtypes) will be enrolled into the registry. In patients with relevant (clinical and/or research) mutations, testing may be extended to biological family members if not already facilitated clinically.

Recruitment Timeline: Ongoing

News You Can Use

Resources for Clinical Research

1. Bio-statistical Support - statistical support for data analysis and experimental planning. Contact Stacy Heilman @ 404-727-4819
2. Clinical Interaction Research Site - replaces the GCRC, and provides facilities and services to aid the conduct of clinical trials. Contact Christine Spainhour @ 404-785-0400
4. Research Processing Lab - provides research sample processing, storage, and shipping. Contact Diana Worthington-White at 404-785-1721

Helpful Links

Atlanta Clinical and Translational Science Institute
Pediatric Nephrology Open Protocols
Emory Children’s Research Office
NIDDK Research Centers for Excellence in Pediatric Nephrology
Research Matters

Collaborations with Pediatric Research Center

With the increase in the number of protocols that the division of pediatric nephrology has been engaging in, particularly pharmacokinetic/pharmacodynamic studies, the pediatric research center (PRC) has proven to be invaluable.

The PRC has been instrumental in the recent success of the clinical trials examining the use of eculizumab in adolescent patients with plasma therapy resistant aHUS. The PRC provides the pharmacy services. This has served as a great comfort to research participants as they can complete their research visits in a patient-friendly environment with experienced staff.

Financial Interest in Research Reporting Using eCOI

Beginning in January 2010, all Investigator Financial Interest Reports related to Research (formerly the OSP SPAF COI form) should be completed on-line through eCOI.

All Investigators are required to report certain financial arrangements (for themselves, spouse/domestic partner, and dependent children) with external entities that are related to the specific research project. These financial arrangements are often referenced as Significant Financial Interests.

Please reference the quick-start guide on how to report financial interests when routing a new research proposal, which is available at http://www.coi.emory.edu/COI_documents/new_proposals_quick_start_guide.pdf

New Spring Quarterly Protocols

Abbott Registry Study—The objective of this study is to observe the safety of paricalcitol utilization in pediatric patients being treated for secondary hyperparathyroidism (SHPT). Patients will be followed for a minimum of 3 months and up to approximately 36 months to monitor the incidence of hypercalcemia.

Novartis Hypertension Study—This double-blind 8 week study will evaluate dose response, efficacy and safety of aliskiren in children 6 – 17 years old with hypertension at low, mid and high weight-based doses. This study is being conducted to support monotherapy registration of aliskiren for the treatment of hypertension in children 6-17 years of age.

The success of any of our protocols depends on the support of all of our nurses and staff. Please take the time to review the particular research protocols highlighted in this issue and recommend any eligible patients to Margo Kamel, mkamel@emory.edu. Also, please feel free to make any suggestions that you feel will facilitate the conduct of any research project.

Thank you for all of your help!

Sincerely, Margo Kamel