

## **Clinical Trial Studies**

### **Resident**

#### **NSF Study**

**Objective:** The purpose of this study is to assess the magnitude of potential risk with the administration of Magnevist® Injection in patients with moderate to severe renal impairment for the development of NSF based on biopsy confirmation or, if a biopsy report is not available, the development of any 2 or more of the following 3 cutaneous skin changes present on the extremities, which have been characterized in the medical literature as being “consistent with NSF skin changes: (a) hyperpigmentation, (b) hardening, and (c) tethering.

**PI:** Richard D. White, MD

**Sub-Investigators:** H. Martin Northup, MD

**Sponsor:** Bayer Healthcare

#### **CNS 3**

**Objective:** To demonstrate the superiority of combined unenhanced and enhanced MRI compared to unenhanced MRI based on the evaluation of degree of contrast, assessment of border delineation, internal morphology of lesions

**PI:** Robert Booth, MD

**Sub-Investigators:** D. Castro, MD, H. Martin Northup, MD, I. Cohen, D. Kantor, D. Siragusa

**Sponsor:** Bayer Healthcare

#### **ACRIN/RTOG**

**Objective:** To evaluate the ability of peak standardized uptake (SUV) for FDG obtained at each institution shortly after definitive chemoradiation (post-treatment) to predict long-term survival in inoperable Stage 11/111 NSCLC.

**PI(s):** S. Ozdemir, MD, ACRIN; C. Nichols, MD, RTOG

**Sub-Investigators:** B. McCook, MD, R. Goodwich, MD

**Sponsors:** RTOG, ACRIN

#### **RADIATION THERAPY ONCOLOGY GROUP - RTOG 0622**

**Objective:** To assess the effectiveness of Samarium 153 administration, as determined by a 30% decline in the PSA within 12 weeks, as compared to baseline, in a population of men with high risk, clinically non-metastatic prostate cancer after a radical prostatectomy.

**PI(s):** C. Nichols, MD;

**Sub-Investigator:** B. McCook, MD, R. Goodwich, MD

**Sponsor:** RTOG

#### **CNS 2 Study**

**Objective:** The primary objective of this study is to demonstrate improvement of combined unenhanced and gadobutrol-enhanced magnetic resonance imaging (MRI) compared to unenhanced MRI based on the evaluation of the following: total number of lesions detected, degree of contrast enhancement, assessment of border delineation, and internal morphology of lesions.

**PI: Robert Booth, MD**

**Sub-Investigators:** D. Siragusa, MD, D. Kantor, MD, H. Northup, MD, and I. Cohen, MD

**Sponsor:** Bayer Healthcare

### **CLEVER Study**

**Objective:** The purpose of study is to determine if the effect of the combination treatment cardedilol MR+ lisinopril is superior to the effect of combination treatment atenolol and lisinopril, and to lisinopril administered without B blockade on left ventricular mass regression after 18 months of treatment in subjects with HTN and LVH.

**PI:** M. Wilke, MD

**Sub-Investigators:** A. Miller, MD, C. Klassen, MD, M., Nguyen, MD

**Sponsor:** GSK

### **SPARC Study**

**Objective:** The purpose of this study is to assess the impact of Myocardial Perfusion, CT Coronary Angiography, and combined Myocardial Perfusion-CTA imaging on post-test resource utilization as measured by referral to early catheterization (<90 days after the index noninvasive imaging study). Also, the study is to determine the incremental prognostic value of stress SPECT, stress PET, CTA, and PET/CT for predicting cardiac death and nonfatal myocardial infarction.

**PI:** Richard D. White, MD

**Sub-Investigators:** M. Nguyen, MD, C. Klassen, MD, S. Ozdemir, MD, and D. Angiolillo, MD

**Sponsor:** Brigham & Women's Hospital

### **Sponsored Research**

#### **James & Esther King Biomedical Research Program**

**Objective:** To investigate the simultaneous acquisition of calcium scoring, coronary angiogram, and perfused blood volume in the myocardium during cardiac CT exams—providing more info in fewer scans & potentially less radiation dose

**PI:** Kevin R. Johnson, PhD

**Mentor:** Richard D. White, MD

**Sponsor:** Florida DOH

### **Device Studies**

**PI:** Daniel A. Siragusa

**Title:** Cordis Enterprise Study

WIRB: 11/1/2009

**Objective:** The Cordis Enterprise Vascular Reconstruction Device and Delivery System is authorized by the Federal Law for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms arising from a parent vessel with a diameter of  $\geq 3$ mm and  $\leq 4$  mm

**Sponsor:** Cordis Neurovascular, Inc., a Johnson & Johnson Company