MICROVENTION CLINICAL RESEARCH

Quick Reference of Trials/Studies/Registries Presently Underway

Aneurysm Wall Histology Registry

Multi-center, prospective, registry to evaluate aneurysm wall histology and to determine the relative and absolute differences in histological changes as seen in the tissue samples comparing this to the Cerebrospinal Fluid (CSF) and blood plasma samples

- 50 specimens total
- Aneurysm wall biopsy – at open surgical clipping
- CSF – collection from cisterns during surgical exposure
- Blood plasma – pre-operatively
- www.AneurysmHistology.com
- ClinicalTrials.gov Identifier: NCT01444664
- PI – Dr. Raymond Turner – Medical University of South Carolina, Charleston, South Carolina, USA

FRED™ Flow Re-Direction Endoluminal Device

Pivotal study of the MicroVention, Inc. Flow Re-Direction Endoluminal Device Stent system in the treatment of intracranial aneurysms

- Multi-center, prospective, single-arm study
- 127 subjects with 30 day, 180 day, and 12 month clinical follow-up, plus 180 day and 12 month angiographic follow-up
- Ruptured (>60 days since occurrence) – unruptured intracranial aneurysms
- ClinicalTrials.gov Identifier: NCT01801007
- PI – Dr. Cameron McDougall - Barrow Neurological Institute, Phoenix, Arizona, USA

GEL THE NEC Gaining Efficacy Long Term: HydroSoft®, an Emerging, New Embolic Coil

Multi-center, prospective, registry to deploy HydroSoft® coils as finishing coil

- 600 subjects total with a follow-up between 6-18 months
- Ruptured - unruptured intracranial aneurysms 3-15 mm
- Outcomes - safety and efficacy
- www.gelthenec.org
- ClinicalTrials.gov Identifier: NCT01000675
- PI – Dr. David Kallmes – Mayo Clinic, Rochester, Minnesota, USA
- Contact Beth Connelly at: connelly.beth@mayo.edu

GREAT German Randomized Endovascular Aneurysm Trial

Multi-center, randomized, controlled trial of endovascular management of aneurysms comparing HydroSoft® coils versus standard bare platinum coils

- France and Germany only
- Ruptured – unruptured intracranial aneurysms 4-12 mm
- Target of 500 subjects with 6 month and 18 month follow-up
- www.thegreatstudy.org
- PI – Dr. Christian Taschner – Freiburg University Hospital, Freiburg, Germany

HEAT New Generation Hydrogel Endovascular Aneurysm Treatment Trial

Multi-center, multi-national, prospective, randomized, controlled study of new generation Hydrogel coils versus bare platinum coils (HydroFrame® /HydroCoil® /HydroFill® /HydroSoft® coils vs. any platinum coil)

- Up to 600 subjects total with 3-12 month and 18-24 month follow-up
- Ruptured – unruptured intracranial aneurysms 3-14 mm
- ClinicalTrials.gov Identifier: NCT01407952
- PI – Dr. Bernard Bendok – Northwestern University Hospital, Chicago, Illinois, USA
- Contact: HEATtrial@northwestern.edu and/or Jennifer Ward, MBA, CCRD at jward@nmff.org

HYBRID HYdrogel Coil Versus Bare Platinum Coil in Recanalization Imaging Data Registry

Multi-center, prospective, randomized, open label blind study to compare the efficacy of Hydrogel coils versus bare platinum coils

- Japan sites only
- 500 subjects total (250/arm) with 12 month follow-up
- Ruptured - unruptured intracranial saccular aneurysms 7-20 mm
- PI - Dr. Nobuyuki Sakai - Kobe City Medical Center General Hospital, Kobe City, Japan

LVIS™ Low-profile Visualized Intraluminal Support

Pivotal study of the MicroVention, Inc. Neurovascular Self-Expanding Stent system LVIS™ and LVIS™ Jr. in the treatment of wide-necked intracranial artery aneurysms

- Multi-center, prospective, single arm study
- Ruptured (>30 days after occurrence) - unruptured wide-necked intracranial saccular aneurysms
- 137 subjects with 30 day, 6 month, and 12 month clinical follow-up, plus 12 month angiographic follow-up
- ClinicalTrials.gov Identifier: NCT01793792
- PI - Dr. David Fiorella – Stony Brook University Medical Center, Stony Brook, New York, USA

TRAIL TReatment of Aneurysms Intracranial with the Low-profile Visualized Intraluminal Support System

Multi-center, prospective, observational study to evaluate the performance and safety of the LVIS™ and LVIS™ Jr. devices in the treatment of intracranial aneurysms

- France only
- 90 subjects with 6 month and 18 month clinical and anatomical follow-up
- Ruptured – unruptured saccular intracranial aneurysms
- PI – Dr. Michel Piotin – Hôpital de la Fondation Rothschild, Paris, France
  and Dr. Charbel Mounayer – Hôpital Dupuytren, Limoges, France

PRET Patients Prone to Recurrence after Endovascular Treatment

Multi-center, multi-national, prospective, randomized trial of endovascular management of aneurysms prone to recurrence after endovascular treatment comparing hydrogel-coated and platinum standard coils

- 500 subjects total (250/arm)
- PRET I – Aneurysms 10 mm or larger
- PRET II - Any recanalized aneurysms subjectively treatable by coiling procedure
- www.pretstudy.org
- ClinicalTrials.gov Identifier: NCT00626912
- PI – Drs. Daniel Roy, Jean Raymond – CHUM – Notre-Dame Hospital, Montreal, Quebec, Canada
- Contact Ruby Klink at: ruby.klink@crchum.qc.ca

Completed Studies

BHR Brazilian HydroSoft® Registry

Study focused on safety and efficacy of the HydroSoft® coil, as well as evaluating short term clinical and angiographic outcomes

- Prospective, multi-center, registry
- 150 subjects with intracranial aneurysms less than 10 mm
- PI - Dr. Francisco De Lucca - Hospital Biocor, Minas Gerais, Brazil

FAR French Aneurysm Registry

Multi-center registry focused on evaluating the safety profile and aneurysm occlusion feasibility and stability associated with the HydroSoft® coil

- 89 subjects enrolled (102 intracranial aneurysms evaluated) with its primary endpoint of recanalization at 6 months
- Independent Core Lab
- PI – Pr. Alain Bonafe – CHU Montpellier, France

HCAT HydroCoil® Cerebral Aneurysm Treatment Trial

Multi-center, multi-national, randomized, control study to compare Hydrogel coils to non-Hydrogel coils

- 221 subjects enrolled with 6-12 month and 18-24 month follow-up
- Ruptured - unruptured intracranial aneurysms 5-20 mm
- www.hcatrial.org
- ClinicalTrials.gov Identifier: NCT01195129
- PI – Dr. Avery Evans – University of Virginia, Charlottesville, Virginia, USA

HELPS HydroCoil® Endovascular Aneurysm OccLusion and Packing Study

Multi-center, multi-national, randomized, controlled trial comparing patients that were allocated to the HydroCoil® system versus standard bare platinum coils

- PI – Philip White M.D.
- The Lancet 2011;377:1655-1662. White PM, Lewis SC, Gholkar A, Sellar RJ, Nasher H, Cognard C, Forrester L, Wardlaw JM for the HELPS trial collaborators

SAHR South American HydroFrame® / HydroSoft® Registry

Study focused on the safety and efficacy of the HydroFrame® and HydroSoft® coils vs. bare platinum, as well as evaluated short term outcomes at 6 to 12 months

- Prospective registry
- 160 subjects (80/arm) with 6 to 12 months follow-up
- Unruptured intracranial aneurysms 3-10 mm
- www.SAHRegistry.org
- PI – Dr. Luis Lemme Plaghos - Centro Endovascular Neurologico, Buenos Aires, Argentina

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