Overview of Coil Trials and Registries

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Disclosures

- No financial interest in any product or manufacturer mentioned herein.

Talk aims

- Review coiling trials and provide updates

HEAT Trial - Hydrogel vs Bare Platinum

HEAT -Hydrogel Endovascular Aneurysm Treatment trial	
National PI	***Bernard Bendok, MD***
Design	***Prospective, randomized, post-market clinical trial***
Aim	***Compare 2nd generation hydrogel coil technology to bare platinum. Hydroframe/Hydrocoil/Hydrofill/Hydrosoft***
Subjects	***Ruptured and unruptured; 3-14 mm***
Primary outcome	***Aneurysm recurrence at any time during follow up (24 months)***
Updates: • ***425 patients enrolled to date (target 600)***	

Gel-the-Nec Registry - Hydrosoft as finishing coil

Gel-the-Nec - Gaining Efficacy Long Term: Hydrosoft, an Emerging, New Embolic Coil	
National PI	***David Kallmes, MD***
Design	***Post-market, Multi-center prospective registry to deploy Hydrosoft coils as a finishing coil***
Aim	***Gain robust clinical data in a large set of patients to better understand the advantages and disadvantages of hydrosoft coils***
Subjects	***600 subjects, ruptured & unruptured aneurysms 3 - 15 mm***
Primary outcome	***Safety and efficacy***
Updates: • ***Enrollment complete*** • ***600 patients enrolled*** • ***Follow-up is underway*** • ***Periprocedural outcomes will be submitted for publication soon***	

PRET Trial - Hydrogel vs platinum in aneurysms prone to recurrence

PRET - Patients prone to recurrence after endovascular treatment	
National PI	***Daniel Roy MD, Jean Raymond MD***
Design	***Multi-center, prospective, randomized trial of management of aneurysms prone to recurrence comparing hydrogel and platinum coils***
Aim	***Compare hydrogel coils to bare platinum coils***
Subjects	***447 (250 large aneurysms (>10mm), 197 recurrent)***
Primary outcome	***Recurrence rate of target aneurysm***

Updates:

- ***Completed***
- ***Peri-procedural results AJNR 2014; 35(9): 1667-76.***

1. ***No difference between groups for indices to assess safety up to 30 days.***
2. ***Operator-assessed angiographic outcomes were satisfactory (complete occlusion or residual neck) in 339/444 (76.4%) of patients with no significant difference between groups.***

- ***Follow up data coming***

FAR Registry - safety, occlusion feasibility, and stability of hydrosoft coil

FAR - French Aneurysm Registry	
National PI	***Alain Bonafe, MD***
Design	***Multi-center registry***
Aim	***Evaluate safety profile and aneurysm occlusion feasibility and stability associated with the hydrosoft coil***
Subjects	***102 aneurysms***
Primary outcome	***Recanalization at 6 months***
Updates: • ***Completed*** • ***Publication pending***	

GREAT - German trial comparing hydrosoft vs platinum coils

GREAT - German Randomized Endovascular Aneurysm Trial	
National PI	***Christian Taschner, MD***
Design	***Multi-center randomized controlled trial***
Aim	***Evaluate the safety, efficacy, and long-term outcomes of the hydrosoft coil***
Subjects	***503 patients, aneurysms 4-12 mm***
Primary outcome	***Recanalization at 6 and 18 month follow up***
Updates: • ***Completed*** • ***Publication expected late 2014***	

GELATIN Registry

GELATIN -Hydrogel balloon assisted intracranial aneurysm coiling registry	
National PI	***Sam Zaidat, MD***
Design	***Prospective, single arm***
Aim	***Evaluate balloon assisted coiling with the Scepter balloon and hydrogel coils for the treatment of intracranial aneurysms.***
Subjects	***Subjects***
Primary outcome	***Aneurysm recurrence rate at 6 ± 3 month follow up.***
Updates: • ***Currently enrolling.***	

ACE Registry – PC 400 System coils

ACE – Study of the Penumbra Coil 400 System to Treat Aneurysm	
Study Director	***Siu Po Sit, PhD***
Design	***Prospective, multi-center registry***
Aim	***To gather post-market data on the PC 400 system***
Subjects	***2,000 patients with intracranial or peripheral aneurysms. Up to 100 centers.***
Primary outcome	***• Packing density with the number of coils implanted • Fluoro exposure • Procedural device-related SAEs***
Updates: • ***Enrollment: 505 patients (70 centers)***	

VOLCAN Registry

VOLCAN – A Volumetric Coiling in Aneurysm Registry of the Penumbra Coil 400 System in France	
PI	***Laurent Pierot, MD***
Design	***Prospective, multi-center***
Aim	***Registry of patients treated with PC400 system***
Subjects	***200, 20 centers***
Primary outcome	***Packing density, fluoro time, immediate SAEs, 1 year Raymond Scale occlusion***
Updates: • ***Currently recruiting***	

TARGET Registry

TARGET Intracranial Aneurysm Coiling Registry	
National PI	***Sam Zaidat, MD MS***
Design	***Prospective, open label***
Aim	***Clinical efficacy and safety of Stryker Target 360 and Target 2D coils***
Subjects	***150***
Primary outcome	***Packing density***

Updates:

- ***Enrollment complete***
- ***Preliminary results: Packing density 25.7% +/- 16.3% and was main predictor of complete aneurysm occlusion.***
- ***Second arm to launch***

  Will look at Nano technology. Up to 150 additional patients.

FEAT Trial –18 coils vs 10 coils

FEAT -Framing Eighteen Coils in cerebral Aneurysms Trial	
National PI	***J Mocco, MD, MS***
Design	***Prospective, randomized***
Aim	***Compare use of 0.014 – 0.0155 ("18 coils") vs smaller diameter standard "10 coils" in mid-size aneurysm (6-14 mm) treatment.***
Subjects	***650 enrolled across 25 sites***
Primary outcome	***Occlusion rate***
Updates: • ***Currently enrolled: 150*** • ***Sites: 19*** • ***Estimated last enrollment: January 2018***	

NANO – Small aneurysm coiling

NANO EffectiveNess and SAfety of Small ANeurysm COiling Trial	
National PI	***Avery Evans, MD***
Design	***Prospective, (non-inferiority to large aneurysm coiling)***
Aim	***Compare safety and efficacy of treating small aneurysms with coils to historically reported rates for larger aneurysms.***
Subjects	***Ruptured or unruptured, aneurysm < 4 mm***
Primary outcome	***Composite of technical failure (inability to coil aneurysm) and complication leading to permanent neurologic injury or death. Angiographic recurrence at 12-18 months.***
Updates: • ***Currently recruiting.***	

LARGE – Flow diversion versus traditional coiling

LARGE –Aneurysm Randomized Trial: Flow Diversion Versus Traditional Endovascular Coiling Therapy	
National PI	***Aquilla Turk, DO***
Design	***Randomized***
Aim	***Endovascular coiling is non-inferior to flow diversion with respect to a combined safety and efficacy endpoint***
Subjects	***• 318*** ***• Aneurysm >/= 10 mm in paraphthalmic, cavernous, or petrous***
Primary outcome	***Greater than 90% angiographic occlusion AND stable (or decreased) aneurysm size on cross-sectional imaging at 180 days. AND free of any major neurologic event (change in NIHSS > 4 points)***
Updates: • ***Recruiting participants***	

Summary

Ongoing coiling trials and registries aim to evaluate

- Hydrogel vs bare platinum coils
- 18 vs 10 coil systems
- Post-market Penumbra 400 system
- Nano coils
- Flow diversion vs traditional coiling