MicroVention® TERUMO

HEAT

New Generation Hydrogel Endovascular Aneurysm Treatment Trial

ClinicalTrials.gov Identifier: NCT01407952

Bernard R. Bendok, MD, FACS, FAANS, FAHA
Head of Neurosurgery, Northwestern University Hospital, Chicago, IL

A randomized controlled trial of New Generation Hydrogel coils versus bare platinum coils in the endovascular treatment of intracranial aneurysms

Study Objective
To compare initial complete occlusion, recanalization, retreatment, and adverse event rates of the Hydrogel coils to those of bare platinum coils

Study Design
International, randomized, prospective, controlled, multi-center trial

Device
Second generation hydrogel coils from the HydroCoil® Embolic System (including the HydroFrame®, HydroFill® and HydroSoft® coils, and future FDA approved Hydrogel coils ("Hydrogel Group") and Platinum coils ("Platinum Group")

Treatment Population
Subjects with intracranial aneurysms between the ages of 18 and 75 years inclusive

Estimated Trial Size
600 randomized subjects

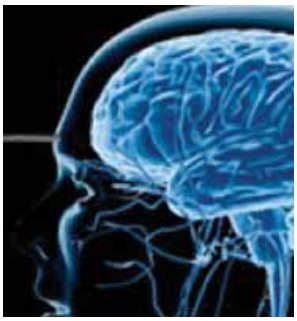
Number of Sites
Approximately 50 sites inside and outside of the U.S.

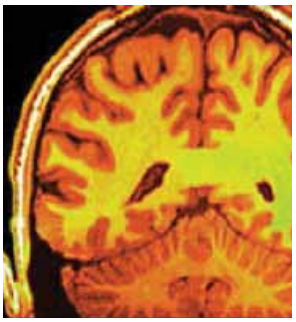
Primary Endpoint
Aneurysm recurrence at any point during follow-up (time frame 24 months) defined as any progression on the Raymond aneurysm occlusion scale.

- **Early follow-up 3-12 months post procedure:** A digital subtraction cerebral angiogram will be performed. MRA can be performed instead of or in addition to the angiogram if considered standard of care at the institution. For subjects enrolled with ruptured aneurysms, an NIHSS score will be obtained.
- **Late follow-up at 18-24 months post procedure:** A digital subtraction cerebral angiogram will be performed. MRA can be performed instead of or in addition to the angiogram if considered standard of care at the institution. For subjects enrolled with ruptured aneurysms, an NIHSS score will be obtained.

Secondary Endpoints
- Packing density as measured by volumetric filling of the aneurysm
- Clinical outcome at 18 to 24 months (mRS)
- Peri-procedural and post-procedural adverse events related to the procedure and/or the device
- Mortality rate
- Initial complete occlusion
- Aneurysm retreatment
- Haemorrhage from target aneurysm during follow-up
- Aneurysm occlusion stability
- Major vs. minor recurrence

Visit Schedule
Baseline, Procedure, 1 day post-coiling, 3 days to 28 days, 3 months to 12 months, 18 months to 24 months





Pricipal Investigator ("PI")
Bernard R. Bendok, M.D.
Northwestern University
Chicago, IL

Study Sponsor
Northwestern University
Chicago, Illinois, USA

Coils in the Trial

Hydrogel Group
- HydroFrame® Coil
- HydroFill® Coil
- HydroSoft® Coil
- Future FDA or HPB (Health Protection Branch) coils

Platinum Group
- Cosmos® Coil
- Complex Coil
- VFC® Coil
- Helical Coil
- HyperSoft® Coil
- Any FDA or HPB (Health Protection Branch) approved or cleared bare platinum coils

Inclusion Criteria

1) Patient is between 18 and 75 years of age (inclusive)
2) Patient has a documented untreated intracranial saccular aneurysm 3-14 mm diameter angiographic lumen, ruptured or unruptured, suitable for embolization with coils
3) For ruptured aneurysms, patients presenting with a Hunt and Hess Grade 1-3 or improving to such a grade before treatment
4) Any type of bare platinum coils and Hydrogel coils are treatment options (all shapes allowed)
5) Patient or next of kin or person with appropriate power of attorney has provided written informed consent
6) Patient is willing and available for study follow-up visits
7) Patient has not been previously entered into this study

Exclusion Criteria

1) Inability to obtain informed consent
2) Patient is <18 or >75 years old
3) Target aneurysm is not saccular in nature (mycotic, fusiform, dissecting)
4) Target aneurysm is >14 mm maximum luminal dimension, <3 mm maximum luminal dimension
5) Target aneurysm has been previously clipped or coiled
6) Target aneurysm is in the physician's estimate unlikely to be successfully treated by endovascular techniques
7) Patient has known hypersensitivity to platinum, nickel, stainless steel or structurally related compounds found in HydroFill®, HydroSoft®, HydroFrame® coils and/or bare platinum coils
8) Baseline Hunt and Hess scale 4 or 5 for ruptured aneurysms
9) Intended use of a flow diverting stent (e.g. pipeline)
10) Subject has concurrent intracranial pathology: (e.g. Moyamoya, Vasculitis documented by biopsy results, AVMs, AV fistulas, Significant atherosclerotic disease (i.e. symptomatic and or >50% narrowing of the parent arteries necessary to traverse in order to coil the target aneurysm), Intracranial Hematoma (unrelated to the target aneurysm), Brain tumors, Vascular tortuosity and other conditions preventing access to target aneurysm)
11) Subject has serious co-morbidities that could confound the study results: Uncontrolled hypertension, Uncorrectable coagulation abnormality; Contraindications for heparin; aspirin or clopidogrel; Uncontrolled Diabetes Mellitus; Organ failure of kidney, liver, heart, or lung; Myocardial infarction within the past 6 months; Cancer likely to cause death within 2 years or less
12) Subject history indicates high risk of non-compliance (e.g., substance abuse, psychosocial issues)
13) Subject has a known history contraindicating contrast dye or iodine that cannot be premedicated prior to coiling procedure (vs. sensitivity which can be safely controlled by antihistamine, steroid, etc.). Medical clearance will be needed for this issue
14) Patients who are unable to complete scheduled follow-up assessments at the enrolling center due to limited life expectancy (<2 years), co-morbidities or geographical considerations
15) Subject is currently breast feeding, pregnant or plans to become pregnant in the next 2 years
16) Major surgical procedure or trauma within 30 days prior to randomization
17) The patient is currently enrolled in another clinical study (device or drug)
18) More than one aneurysm needing treatment at the same time

HydroFrame® Coil

Diameters: 2 – 20mm
Lengths: 2 – 48cm

HydroFill® Coil

Diameters: 2 – 24mm
Lengths: 2 – 50cm

Pre-Expansion / Post-Expansion
.013"/ .016" for 2 – 4mm dia.
.015"/ .018" for 5 – 24mm dia.

HydroSoft® Coil

Diameters: 1.5 – 10mm
Lengths: 2 – 30cm

MicroVention, Inc.
Worldwide Headquarters PH +1.714.247.8000
1311 Valencia Avenue
Tustin, CA 92780, USA
MicroVention UK Limited PH +44 (0) 191 258 6777
MicroVention Europe, S.A.R.L. PH +33 (1) 39 21 77 46
MicroVention Deutschland GmbH PH +49 211 210 798-0
Web **microvention.com**