HEAT: New Generation Hydrogel Endovascular Aneurysm Treatment Trial

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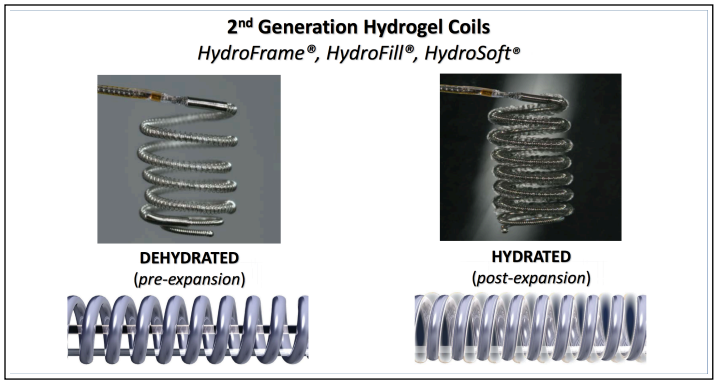
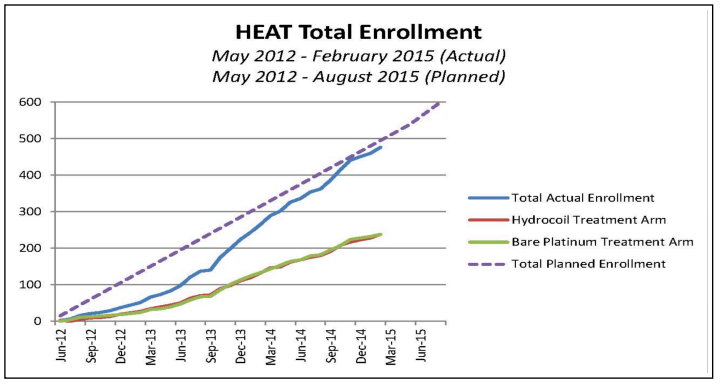


Introduction

Endovascular treatment of intracranial aneurysms has seen significant advances. One major limitation of the endovascular approach is durability of treatment and aneurysm recanalization. To address this issue, one approach has been the development of hydrogel-coated coils. Hydrogel expands upon exposure to blood and thus enhances coil packing density. Higher initial coil packing density may potentially result in lower rates of recurrence. The 2nd Generation HydroCoil Embolic System allows for a higher packing density, higher initial occlusion, lower recanalization, and lower retreatment rates compared to bare platinum coils. Our objective is To compare clinical and angiographic outcomes (initial complete occlusion, recanalization, retreatment, and adverse event rates) in patients receiving 2nd Generation HydroCoil Embolic System versus patients receiving bare platinum coils.

Methods

This is a randomized, controlled, multicenter, post-market clinical trial. Subjects between 18 and 75 years of age with ruptured or unruptured intracranial aneurysms (3-14 mm in size) who are amenable to endovascular treatment are randomly assigned 1:1 to one of two treatment arms: 1) the HydroCoil Embolic System (HES), or 2) bare platinum coils. No bioactive coils, 1st generation HydroCoils or liquid embolics are allowed in the study. In the HES arm, up to 10% of total coil length using bare platinum is allowed if deemed necessary by the investigator. Any type of bare platinum coil may be utilized in the bare platinum arm. Assist-devices can be used at the discretion of the investigator. The duration of the open enrollment phase will be 24 months or until the required number of subjects are enrolled (n = 600). Each subject will have a post-procedure follow-up of at least 18 months. Subjects will be recruited from up to 50 national and international centers. Each Investigational Site will be expected to enroll at least 20 Subjects.



Results

A total of 490 patients have been enrolled to date in the study. The study is still ongoing.

Conclusions

A limitation of endovascular aneurysm treatment is recurrence. This trial aims to answer the question of whether the new generation hydrogel coil reduces recurrence rates when compared to bare platinum coils.

Learning Objectives

To check whether new generation hydrogel coil reduces the recurrence rates of intracranial aneurysms when compared to bare platinum coils.