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HEAT: New Generation Hydrogel Endovascular Aneurysm Treatment Trial Update Rami James N Aoun MD; Mithun G. Sattur MCh; Andrew R Pines MA; Mathew Welz; Jennifer D Ward MBA; Byron K Yip BA;

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Introduction

Aneurysm recanalization constitutes a major limitation in the endovascular treatment of intracranial aneurysms using conventional bare platinum coils. Hydrogel is a synthetic polymer that expands upon exposure to blood. The development of platinum coils coupled with hydrogel polymers, hence, may potentially result in decreased rates of recurrence by way of enhanced coil packing density. The main objective of the HEAT trial is to compare the clinical and angiographic outcomes in patients treated with 2nd generation hydrogel coils versus patients treated with bare platinum coils.

Methods

The HEAT trial is a multi-center randomized controlled phase 4 clinical trial (n=600, 46 study centers in the U.S. and Canada) Patients are randomized with a 1:1 assignment to one of two treatment arms: 2nd generation hydrogel coils (up to 10% of total coil length using bare platinum allowable, if deemed necessary) or bare platinum coils. The key inclusion criterias are subjects aged 18-75 with a previously untreated intracranial saccular aneurysm (3-14 mm in diameter), ruptured or unruptured, and suitable for embolization with coils. No bioactive coils, 1st generation hydrogel coils or liquid embolics are allowed. Coil-assist devices may be utilized during treatment of the target aneurysms. Study follow-up duration is 18-24 months.



Results

A total of 600 subjects (297 randomized to hydrogel treatment arm and 303 randomized to bare platinum treatment arm) have been enrolled in the study. The study is now closed to accrual and pending completion of follow-up data.

Conclusions

The HEAT trial may answer the question of whether 2nd generation hydrogel coils are superior to bare platinum coils in reducing aneurysm recurrence rates.

Learning Objectives

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