

The INVEST Trial: A Randomized, Controlled Trial to Investigate the Safety and Efficacy of Image Guided Minimally Invasive Endoscopic Surgery With Apollo VS Best Medical Management for Supratentorial Intracerebral Hemorrhage

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Introduction

Spontaneous intracerebral hemorrhage (ICH) is a common subtype of hemorrhagic stroke, with the poorest prognosis of all stroke subtypes. Today's standard of care for these patients result in high mortality, lengthy recovery times, and low functional improvements. The goal of the INVEST trial is to evaluate the safety and efficacy of minimally invasive hemorrhage evacuation with the Apollo device (Penumbra Inc, Alameda, CA) compared to medical management.

Methods

The INVEST study is a prospective multicenter US trial designed to enroll 222 patients at up to 30 centers. Patients between the ages of 22-80 or <85 with baseline mRS=0 or 1, NIHSS of at least 6, GCS of 5-15, and presenting with a moderate to large volume supratentorial ICH (30-80 cc) within 24h of onset are eligible for enrollment. Qualifying patients will be randomized (1:1) to either minimally invasive surgery (MIS) with Apollo or to best medical management (MM) following a stability scan. Follow up for each patient will be conducted at days 3, 7, discharge, 30, 90, 180, and 360 from enrollment. The primary endpoints are mRS 0-3 at 180 days and mortality at 30 days. Secondary endpoints include stroke impact scale (SIS) -mobility, SIS-ADLs and EQ-5D-5L at 180 days, and length of hospitalization. All imaging will be assessed by an independent core laboratory.

Results

Centers are currently in the process of initiation with a potential start date forthcoming. Updated information regarding trial progress will be discussed at the time of presentation.

Learning Objectives

By the conclusion of this session, participants should be able to 1) identify the patients who are candidates for the INVEST trial, 2) discuss the potential role for MIS in ICH management, 3) discuss the function of the Apollo system.

Conclusions

The INVEST is designed to provide an assessment of the safety and efficacy of Apollo MIS for the treatment of spontaneous supratentorial ICH.

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