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Minimally Invasive Barrow Early Aggressive Removal of Intracranial Hemorrhage (MI BEAR ICH): A Protocol of a multi-center randomized controlled trial

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Introduction

Primary intracranial hemorrhage causes 15 -20% of all strokes. The estimated 30-day-case fatality rate is 30-55%. The goal of the MI BEAR ICH trial is to compare the safety, clinical efficacy, and economic benefits of early aggressive minimally invasive BrainPath mediated surgical evacuation of ICH to the Minimally Invasive Surgery Plus Rt-PA for ICH Evacuation (MISTIE) paradigm.

Methods

A multi-center randomized clinical trial comparing early (within 72 hours) BrainPath mediated surgical evacuation of ICH to minimally invasive thrombolytic evacuation of ICH. The primary efficacy end point is the percentage of clot evacuated. The primary safety endpoints include: 30-day mortality rate, 7-Day intervention-related rate of neurological deficits, 72 hours re-bleeding rate, 30-Day infection rate. The primary economic endpoint is the cost per quality-adjusted life-years (QALY) gained through either intervention measured at time of discharge from hospital and at various time intervals. Secondary endpoints include: Functional improvement (uw-mRS) at 90 days, shift in the degree of disability among the two groups, difference in the rate of functional improvement between the two groups, difference in the overall mortality rate between the two groups, difference in peri-hematoma edema size, length of ICU stay, difference in rate of ICU-related complications.

Results

Centers are currently being recruited. The goal is 10 centers for a total of 40 patients. Updates will be discussed at the time of the presentation.

Conclusions

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Learning Objectives

Identify different Minimally invasive approaches for evacuation of ICH

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