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MIND study

The MIND study involving the ARTEMIS Penumbra System.

Minimally Invasive Neuro Evacuation Device (MIND): A clinical study evaluating the safety and efficacy of the ARTEMIS™ neuro evacuation device in the treatment of intracerebral hemorrhage (ICH).

Critical Summary

Objective: To evaluate whether minimally invasive aspiration using ARTEMIS can safely reduce hematoma volume and potentially improve clinical outcomes in patients with spontaneous ICH.

Study Design: - Prospective, multicenter, single-arm observational study. - Sponsored by Penumbra Inc. - Involved patients with deep ICH (e.g., basal ganglia, thalamus) eligible for minimally invasive evacuation. - Primary endpoints:

- 1. **Safety** (mortality, procedure-related complications).
- 2. **Efficacy** (volume reduction, midline shift, functional outcomes like mRS).

| Key Strengths:

- Real-world data from multiple centers. - Use of modern, targeted aspiration technique (ARTEMIS catheter). - Focused on deep hematomas, often harder to access surgically. - Early results show significant hematoma volume reduction in most patients. - Procedure generally well tolerated, with low perioperative complication rates.

\(\Limitations and Critique:

1. Lack of control group:

1. Being a **single-arm study**, it lacks a comparison against **conservative treatment** or **other surgical approaches** (e.g., craniotomy, MISTIE-style catheter+lysis).

2. Functional outcomes unclear:

- 1. Volume reduction was achieved, but **meaningful clinical recovery** (e.g., return to independence) varies widely by center and patient selection.
- 2. Small sample size so far makes it hard to generalize.

3. Timing of intervention:

1. There's variability in **when** patients were treated (early vs. delayed aspiration), which affects

the results.

- 2. No clear guidelines yet on optimal **time window** for ARTEMIS use.
- 4. No long-term follow-up published yet:
 - 1. Cognitive and neurological outcomes beyond 90 days are not well documented.
- 5. Commercial interest:

1. As it's **industry-sponsored**, results must be interpreted carefully with independent validation.

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[] Conclusion:

The MIND study confirms that the ARTEMIS™ system is: - Technically feasible, - Safe for aspiration of deep ICH, - Effective in reducing hematoma volume.

But it stops short of proving that this translates into **better functional outcomes**, especially compared to **medical management**.

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| What's Needed Next:

- A **randomized controlled trial (RCT)** comparing ARTEMIS vs. **standard care** or vs. other minimally invasive techniques. - Stratified analysis of **ICH volume, location, and timing**. - Cost-effectiveness evaluations. - Long-term outcome tracking.

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