Study Protocol

Title

Temporary Aortic Occlusion with the Abdominal Tourniquet for Refractory Postpartum Haemorrhage: A Proof-of-Concept Study in a War-Affected Region

Version

1.0

Date

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Ethics Approval

Approved by Olexandrivska Hospital Ethics Committee (Approval number: 2024/EC/128094)

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1. Background and Rationale

Postpartum haemorrhage (PPH) remains the leading cause of maternal mortality globally, especially in low-resource and crisis-affected settings. In Ukraine, full-scale war has disrupted medical infrastructure, limiting access to timely surgical interventions and blood transfusion.

The AAJT-S (Abdominal Aortic and Junctional Tourniquet – Stabilized) is an FDA-approved device for temporary aortic occlusion in trauma, but its use in obstetrics is not well studied. This study aims to evaluate the feasibility, safety, and preliminary clinical efficacy of AAJT-S in controlling refractory PPH due to uterine atony in a wartime environment.

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2. Objectives

Primary Objective:

- To assess whether the AAJT-S device can temporarily and safely control severe PPH in a resource-limited, high-risk setting.

Secondary Objectives:

- To describe feasibility of AAJT-S deployment by obstetric teams.
- To evaluate maternal hemodynamic stabilization and procedural outcomes.

- To monitor for short- and long-term complications (thrombosis, ischemia, infection, renal dysfunction).

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3. Study Design

- Design: Prospective, open-label, non-randomized, proof-of-concept
- Duration: December 2024 – April 2025
- Setting: Olexandrivska Hospital, Zaporizhzhia, Ukraine
- Sample Size: 4 patients

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4. Inclusion/Exclusion Criteria

Inclusion Criteria:

- Age ≥18 years
- Primary PPH with blood loss >1000 mL
- Refractory to uterotonics and uterine balloon tamponade
- Oral informed consent obtained

Exclusion Criteria:

- PPH due to trauma, coagulopathy, or retained placenta
- Inability to provide informed consent

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5. Intervention

Application of the AAJT-S device over the upper abdomen (inflated to 250 mmHg) to achieve temporary aortic occlusion for ≤60 minutes. Device application was done following persistent bleeding despite standard therapy.

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6. Procedures

- Initial PPH management per hospital protocol: oxytocin, misoprostol, methylergometrine, tranexamic acid, uterine massage, balloon tamponade
- AAJT-S deployed in case of ongoing bleeding >1000 mL
- Device monitored and deflated after stabilization or readiness for surgery
- Surgical treatment (compression sutures, artery ligation) performed if bleeding resumed
- Data captured: demographics, interventions, outcomes, adverse events
- Follow-up: inpatient daily assessments, phone monitoring post-discharge, pelvic ultrasound at 6 and 12 months postpartum

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7. Outcomes

Primary Outcome:

- Control of bleeding within 2 minutes after AAJT-S application

Secondary Outcomes:

- Surgical readiness time gained
- Total blood loss and transfusion requirements
- Postoperative complications
- Long-term recovery indicators

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8. Statistical Considerations

Descriptive statistics only (medians, ranges); no hypothesis testing or power calculation due to pilot nature. Outcomes presented per individual case.

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9. Ethical Considerations

- Approved by the institutional ethics committee (2024/EC/128094)
- AAJT-S used off-label with oral informed consent
- Risks and rationale explained to each participant

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10. Dissemination Plan

- Results to be submitted for peer-reviewed publication
- Presented at conferences on maternal health and obstetric innovation