Statistical Analysis Plan

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. Objectives

1.1. Primary Objective

- To assess the feasibility and preliminary effectiveness of the AAJT-S device in controlling refractory postpartum haemorrhage (PPH) due to uterine atony in a war-affected, resource-limited setting.

1.2. Secondary Objectives

- To evaluate the safety profile of the AAJT-S device (device-related complications, thrombotic events, ischemic injuries, infection).
- To assess the duration of bleeding control and time to definitive surgical intervention.

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2. Study Design

- **Design**: Prospective, single-center, open-label, non-randomized, proof-of-concept study.
- **Sample Size**: 4 patients
- **Analysis Type**: Descriptive statistics only. No inferential testing or hypothesis-driven comparisons will be performed due to small sample size and exploratory nature.

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3. Analysis Populations

- **Full Analysis Set (FAS)**: All patients who received AAJT-S for refractory PPH.
- **Safety Population**: Identical to FAS; all patients who underwent device placement and were monitored until discharge.

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4. Variables

4.1. Baseline Characteristics

- Age (years)
- Gravida and Para
- Gestational Age at delivery (weeks + days)

4.2. Effectiveness Outcomes

- **Time to bleeding control** (minutes from inflation to cessation of visible bleeding)
- **Total duration of AAJT-S placement** (minutes)
- **Definitive surgical interventions performed** (Yes/No; type of procedure)
- **Total cumulative measured blood loss (CMBL)** (mL)
- **Need for blood transfusion** (Yes/No; units PRBC and FFP)

4.3. Safety Outcomes

- **Thrombotic events** (Yes/No)
- **Ischemic injury** (Yes/No)
- **Device-related complications** (e.g., skin necrosis, incorrect placement)
- **Infectious complications** (e.g., sepsis, wound infection)
- **Readmissions** or complications during postpartum follow-up (Yes/No)

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5. Statistical Methods

5.1. Descriptive Analysis

- **Continuous variables**: summarized using **median, range (min–max)**.
- **Categorical variables**: presented as **counts and percentages**.

5.2. No inferential statistics

- Given the small sample size, **no hypothesis testing**, **p-values**, or **confidence intervals** will be calculated.
- No missing data imputation will be applied. All available data will be included in descriptive summaries.

5.3. Software

- All analyses will be performed using **Microsoft Excel (Version 16.83)**. No specialized statistical software was used due to the simplicity and exploratory nature of the data.

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6. Data Handling and Quality Assurance

- Clinical data were extracted from patient medical records and entered manually into a study-specific Excel spreadsheet.
- Double-checking was conducted for critical variables (e.g., blood loss, time intervals) by both study investigators.

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7. Limitations

- Small sample size prevents generalizability.
- No control group.
- Estimates of blood loss may be subject to observer bias.