

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effectiveness of Balloon Tamponade with a Condom Catheter versus Using a Sengstaken-Blakemore Tube in Patients with Primary Postpartum Hemorrhage

#### Protocol summary

##### Study aim

To compare the efficacy of balloon tamponade versus Sengstaken-Blakemore tube in patients with primary PPH.

##### Design

Open label, randomized controlled trial.

##### Settings and conduct

Gynecology and Obstetrics Department, Bahawal Victoria Hospital, Bahawalpur, Pakistan

##### Participants/Inclusion and exclusion criteria

The inclusion criteria were females aged between 18-40 years of parity 1-6, gravida 1-6, gestational age 31 to 41 weeks, with primary PPH. The exclusion criteria were critically ill patients, those with documented end-organ liver or renal failure (assessed by a medical record), or those with a documented bleeding disorder history, i.e., factor deficiencies (assessed by a medical record). Those with secondary PPH, PPH due to trauma or retained products of the placenta, or those with chorioamnitis were also excluded.

##### Intervention groups

In Balloon tamponade group, females underwent balloon tamponade, and those in Sengstaken-Blakemore group underwent Sengstaken-Blakemore tube insertion and balloon removal after 24 hours.

##### Main outcome variables

Effectiveness will be labeled as failed if there was more than 100 ml of blood loss within 10 minutes after the removal of the balloon tamponade or Sengstaken-Blakemore tube

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221231056999N3**

Registration date: **2024-05-10, 1403/02/21**

Registration timing: **prospective**

Last update: **2024-05-10, 1403/02/21**

Update count: **0**

##### Registration date

2024-05-10, 1403/02/21

##### Registrant information

###### Name

M Aamir

###### Name of organization / entity

RESnTEC, Institute of Research

###### Country

Pakistan

###### Phone

+92 321 6801143

###### Email address

aamir@resntec.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-06-01, 1403/03/12

##### Expected recruitment end date

2024-09-01, 1403/06/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of Balloon Tamponade with a Condom Catheter versus Using a Sengstaken-Blakemore Tube in Patients with Primary Postpartum Hemorrhage

## Public title

Effectiveness of Balloon Tamponade with a Condom Catheter versus Using a Sengstaken-Blakemore Tube in Patients with Primary Postpartum Hemorrhage

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Females aged between 18-40 years Parity 1-6 Gravida 1-6 Gestational age 31 to 41 weeks Primary postpartum hemorrhage (PPH)

### Exclusion criteria:

Critically ill patients Documented end-organ liver or renal failure (assessed by a medical record) Documented bleeding disorder history, i.e., factor deficiencies (assessed by a medical record). Secondary PPH Retained products of the placenta Chorioamnitis

## Age

From **18 years** old to **40 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **64**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Females were divided into two equal groups by a simple lottery method

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Institutional Ethical Review Board

##### Street address

Circular Road, Bahawalpur

##### City

Bahawalpur

##### Postal code

63100

#### Approval date

2023-03-15, 1401/12/24

#### Ethics committee reference number

2363/DME/QAMC

## Health conditions studied

### 1

#### Description of health condition studied

Primary postpartum hemorrhage

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The effectiveness will be labeled as yes, where there was no blood loss for 24 hours after the removal of the pack or Foleys. Effectiveness will be labeled as failed if there was more than 100 ml of blood loss within 10 minutes after the removal of the balloon tamponade or Sengstaken-Blakemore tube.

#### Timepoint

24 hours

#### Method of measurement

Visual evidence of blood loss as per outcome measures.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Balloon tamponade group

#### Category

Treatment - Surgery

### 2

#### Description

Intervention group: Sengstaken-Blakemore group

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Gynecology and Obstetrics Department, Bahawal Victoria Hospital

##### Full name of responsible person

Dr. Shamas un Nisa

##### Street address

Circular Road, Bahawalpur

##### City

Bahawalpur

##### Postal code

63100

##### Phone

+92 301 7706383

**Email**

drshamaamin73@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Bahawal Victoria Hospital

**Full name of responsible person**

Dr. Shamas un Nisa

**Street address**

Circular Road, Bahawalpur

**City**

Bahawalpur

**Postal code**

63100

**Phone**

+92 301 7706383

**Email**

drshamaamin73@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Bahawal Victoria Hospital

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Bahawal Victoria Hospital

**Full name of responsible person**

Dr. Shamas un Nisa

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Circular Road, Bahawalpur

**City**

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**Postal code**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Bahawal Victoria Hospital

**Full name of responsible person**

Dr. Shamas un Nisa

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Bahawal Victoria Hospital

**Full name of responsible person**

Dr. Shamas un Nisa

**Position**

Assistant Professor

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

We are undecided about data sharing right now.

**When the data will become available and for how long**

We are undecided about data sharing right now.

**To whom data/document is available**

We are undecided about data sharing right now.

**Under which criteria data/document could be used**

We are undecided about data sharing right now.

**From where data/document is obtainable**

We are undecided about data sharing right now.

**What processes are involved for a request to access data/document**

We are undecided about data sharing right now.

**Comments**