# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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

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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

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Bahawal Victoria Hospital

**Full name of responsible person**

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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**