

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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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

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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

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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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	Title and more details about the data/document We are undecided about data sharing right now.
Study Protocol Yes - There is a plan to make this available	When the data will become available and for how long We are undecided about data sharing right now.
Statistical Analysis Plan Yes - There is a plan to make this available	To whom data/document is available We are undecided about data sharing right now.
Informed Consent Form No - There is not a plan to make this available	Under which criteria data/document could be used We are undecided about data sharing right now.
Clinical Study Report Yes - There is a plan to make this available	From where data/document is obtainable We are undecided about data sharing right now.
Analytic Code Not applicable	What processes are involved for a request to access data/document We are undecided about data sharing right now.
Data Dictionary Not applicable	Comments