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Equity for suction tamponade access to treat postpartum haemorrhage

Submission date
24/11/2025

Recruitment status
No longer recruiting

Registration date
28/11/2025

Overall study status
Completed

Last Edited
15/07/2026

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Excessive bleeding after birth (postpartum haemorrhage, PPH) is an important complication of childbirth. One method used for treatment is to place a suction catheter inside the uterus (womb) and apply gentle suction to assist the uterus to contract. The only suction device registered for this use in North America is the Jada device which is unaffordable in many settings (USD 1200). The research team have developed a simple suction tube for this purpose (Uterine Suction Tube AssistedTamponade - USTAT). The aim of this study is to test the functioning of this device to be sure that it works as intended without any unanticipated problems.Evaluation will include a randomly allocated control group without use of the USTAT device.

Who can participate?
Pregnant patients over the age of 18 who have increased risk of PPH and no contraindications.

What does the study involve?
Consented participants will be allocated to two groups by a random process. Those in the control group will receive routine care. In addition to routine care, those in the USTA group will have a simple soft plastic tube inserted after the birth of the baby and the placenta (afterbirth). After a normal birth, the tube will be inserted through the vagina (birth passage). At caesarean birth, the tube will be inserted directly into the uterus during the operation, with the end of the tube passed through the vagina. In both cases, the tube will be attached to gentle suction. After 30-60 minutes, if there is no significant bleeding, the tube will be removed, otherwise it will be kept longer if needed to control the bleeding. All participants will be closely monitored for signs of excessive bleeding, which will be managed according to local protocols.

What are the possible benefits and risks of participating?
The main benefit of participating in the study is that one is contributing to research knowledge which will help others in the future. All participants will benefit from very close monitoring of blood loss after birth so that any excessive blood loss can be treated quickly. In addition, the USTAT group may benefit from the effect of the suction tube. Previous studies with similar suction tubes have suggested benefit.

The main risks are discomfort from the procedure, and unanticipated complications. To date no serious complications of suction devices have been identified.

Where is the study run from?
Effective Care Research Unit, University of the Witwatersrand and Walter Sisulu University, Frere and Cecilia Makiwane hospitals, East London, South Africa.

When is the study starting and how long is it expected to run for?
July 2026 to September 2026.

Who is funding the study?
Medical Research Council, UK.

Who is the main contact?
Prof GJ Hofmeyr, Effective Care Research Unit, justhof@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

UK Research and Innovation award reference
UKRI810

Study information

Scientific Title
Equity for suction tamponade access to treat postpartum haemorrhage: The ESTA project

Acronym
The ESTA project

Study objectives
Excessive bleeding after childbirth (postpartum haemorrhage, PPH) causes many deaths worldwide, most of which are avoidable with proper treatment. When medical methods fail, standard care has been to insert a balloon into the uterus and inflate it with saline. A recent development has been to replace this balloon with a suction catheter which assists uterine

contraction thus stopping the bleeding. There is increasing evidence that this is more effective than a balloon, and in the USA, the FDA-approved Jada suction device has become the mainstay of treatment for persistent PPH with >90% success rates.
The current cost of the disposable Jada device (available only in the USA and Canada at US$1200 each) puts it far out of reach of the low-income settings where most PPH deaths occur, leading to global inequity in care. This study will test an affordable suction tube uterine tamponade device to expand access to this life-saving technology.
Suction tube uterine tamponade with off-label use of the Levin stomach tube is included in the South African Integrated Maternal and Perinatal Care Guidelines
The U-STAT Device
In collaboration with Sinapi Biomedical, research and clinical experience with suction tube uterine tamponade has been used with the Levin stomach tube off-label, to develop a low-cost suction device essentially similar to the well-validated Levin stomach tube, but specifically designed for uterine tamponade, as well as a manual suction source to provide suction without the need for electricity.
The overall aim is to improve access to suction tube uterine tamponade for the treatment of PPH globally.
The specific objective of the current study is to conduct 'proof of concept' clinical testing of the purpose-designed device.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/05/2026, Walter Sisulu University Human Research Ethics Committee (Walter Sisulu University Medical School, Mthatha, 5200, South Africa; +27 47 502 2092; fhsrec@wsu.ac.za), ref: WSU HREC 027/2026

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility, Prevention

Study type(s)

Health condition(s) or problem(s) studied
High risk of postpartum haemorrhage

Interventions
The method of randomisation was sequentially numbered, sealed opaque envelopes with allocations in computer-generated random sequence to intervention and routine care.

USTAT purpose-designed soft plastic suction catheter inserted into the uterus after vaginal or caesarean birth to reduce the risk of postpartum haemorrhage in consented participants at high risk of postpartum haemorrhage. Low-pressure suction applied (approx. 100 mmHg). Suction stopped after 30 minutes. If no further bleeding, tube removed. If bleeding resumes, suction continued. If bleeding not controlled within 20 min (or sooner if clinically indicated), proceed to further management according to local standard of care protocols (these might include additional uterotonics, tranexamic acid, compression methods, uterine balloon tamponade or laparotomy).
Control: Routine care

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
USTAT Uterine suction tube assisted tamponade

Primary outcome(s)
1. Combined frequency of adverse device effects and device deficiencies measured using the number of recorded incidents in patient medical records at birth, up to discharge from hospital

Key secondary outcome(s)
1. Blood loss after birth measured using a gravimetric method (ml) at 30 minutes after birth

2. Blood loss > 500 ml measured using a gravimetric method (ml) at 1 hour after birth

3. Blood loss > 1000 ml measured using a gravimetric method (ml) at 1 hour after birth

4. Efficiency of suction measured using ultrasound assessment of residual blood in the uterus or blood expressed from the uterus after tube removal (ml) at 30 minutes after birth

5. Blood pressure, pulse and shock index measured using blood pressure measurement (mmHg); beats per minute; beats per minute/mmHg at 15 minutes after vaginal birth or caesarean

6. Haemoglobin levels measured using an automated haematology analyzer (g/dL) at pre-delivery and post-delivery

7. Blood transfusion (units) from birth to hospital discharge measured using data collected from patient medical notes at at one time point

8. ICU admission at birth to hospital discharge measured using data collected from patient medical notes of incidents at at one time point

9. Death by hospital discharge measured using data collected from patient medical notes of incidents at at one time point

10. Active bleeding from the uterus continuing for more than 10 minutes (main efficacy outcome) measured using data collected from patient medical notes of incidents at at one time point

11. Any adverse event from birth till hospital discharge measured using data collected from patient medical notes of incidents at at one time point

12. Pain experienced (no pain/mild /severe/unbearable) measured using an ordinal scale at after birth

13. Additional interventions to stop bleeding (e.g. more uterotonics, compressive measures, UBT, laparotomy, hysterectomy) after birth till hospital discharge measured using data collected from patient medical notes of incidents at at one time point

14. Was USTAT effectively inserted? measured using a question (yes/no/unknown) and nominal data recording at after birth

15. How easy was it for health care providers to insert the suction tube uterine tamponade (easy /moderately difficult/difficult/failed) measured using an ordinal scale at after birth

16. Did the suction tube remain in place in the uterus until removal measured using a question (yes/no/unknown) and nominal data recording at after birth

17. Did the suction tube establish a good seal (no loss of suction) measured using a question (yes /no/unknown) and nominal data recording at after birth

18. Did the suction tube interfere with or facilitate examination for and management of lower genital tract bleeding after vaginal birth measured using a question (facilitated/interfered /neither/not applicable/unknown) and nominal data recording at after birth

19. Did the suction tube interfere with or facilitate surgical exposure during caesarean birth measured using a question (facilitated/interfered/neither/unknown) and nominal data recording at after birth

20. Was there any blockage of the suction tube measured using a question (yes/no/unknown) and nominal data recording at after birth

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Age 18 years and older
2. Planned vaginal or caesarean birth
3. One or more risk factors for PPH, including:
3.1. Previous PPH
3.2. Hypertension and pre-eclampsia
3.3. Induction of labour
3.4. Emergency caesarean birth
3.5. Anaemia

3.6. Multiple pregnancy
3.7. Polyhydramnios
3.8. Macrosomia
3.9. Antepartum haemorrhage

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Any serious medical conditions

Date of first enrolment
17/07/2026

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
South Africa

Sponsor information

Organisation
Wits Health Consortium

Funder(s)

Funder type

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
IPD will be made available after publication of the primary paper upon reasonable request

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 0.1	21/11/2025	25/11/2025	No	No