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Safer labour induction with the EBLIA balloon

Submission date
12/05/2026

Recruitment status
No longer recruiting

Registration date
15/05/2026

Overall study status
Completed

Last Edited
06/10/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Artificial initiation of labour (labour induction) plays a major and increasing role in childbirth globally. A third of all labours in England are induced artificially and this is mirrored in most high- and medium-income countries. There is good evidence that labour induction reduces risks to the baby in many situations, such as prolonged pregnancy beyond the expected date of birth, without increasing the likelihood of caesarean birth. The increasing global prevalence of labour induction justifies investment in research to improve the effectiveness, acceptability and safety of labour induction methods.
Starting labour off artificially can be difficult and stressful for the parents concerned. There are two main methods: using a medicine taken by mouth or in a drip or inserted into the vagina, or using mechanical means with a balloon which can be passed through the mouth of the womb and then inflated. This is conceptually a more 'natural' process, stimulating release of natural hormones as occurs in spontaneous labour, avoiding complications of amniotomy ('breaking the waters') such as infection, reduced amniotic fluid volume and the need for caesarean birth due to prolonged rupture of membranes and avoiding overstimulating the uterus associated with chemical stimulants.
Research has shown that balloon induction of labour can reduce risk to the baby without increasing caesarean birth rates. The balloon method is therefore becoming more popular than medical methods. However, the balloon method relies on a bladder catheter used off-label (or a similar purpose-designed balloon) which often falls out before labour is established. One then needs to resort to stimulating drugs or breaking the waters, both of which entail risks to the mother and/or baby, and require intensified monitoring of the baby's condition.
A device is needed which can be inflated inside the womb and will not fall out of the mouth of the womb until it has opened up sufficiently to establish labour irreversibly.
We have conducted simulation and clinical studies using threeFoley balloons side by side, with promising results. Twelve of twenty women gave birth naturally with no need for further intervention. With the usual single balloon this would be about one in twenty. The three-balloon method has been used extensively in South Africa for several years and is included in the national guidelines. To simplify the procedure, we have developed a single ring-shaped balloon with a profile similar to the improvised three-balloon combination, and including a second balloon to assist with opening the neck of the womb, called the extended labour induction /augmentation (EBLIA) balloon.

The aim of this study is to conduct a preliminary clinical trial of the EBLIA balloon to show that the device can be used as intended, it is acceptable to participants and staff and it successfully induces labour.

Who can participate?
We will invite pregnant individuals who are due to undergo labour induction, are 18 years or older, and have no serious medical or pregnancy-related complications

What does the study involve?
We will allocate participants who have given fully informed, written consent to two groups using allocation cards in a random sequence. For the one group, we will use the EBLIA balloon to initiate labour. In the other group we will use the usual Foley balloon to initiate labour. All other care will be according to routine policies. We will monitor labour progress and record the outcomes. After the birth of the baby, we will ask participants to complete a short questionnaire about their experience of the labour induction and birth.

What are the possible benefits and risks of participating?
For those allocated to the EBLIA balloon group, there may be benefits, based on our published research using the three side by side Foley balloons, of a more natural labour without the need for breaking the waters or using medical uterine stimulants. The risks are the usual complications of balloon labour induction such as infection, which are rare. For those allocated to the 'usual care' group, the risks will be the normal risks of routine labour induction. All participants will have the inconvenience of additional monitoring during labour and completing the questionnaire. All may benefit from the sense of contributing to medical knowledge which may benefit childbearing individuals in the future.

Where is the study run from?
The study will be conducted at the Frere and Cecilia Makiwane hospitals in East London, Eastern Cape, South Africa

When is the study starting and how long is it expected to run for?
June 2026 to October 2026

Who is funding the study?
The study is funded by a grant from United Kingdom Research and Innovation, Medical Research Council (UK)

Who is the main contact?
Prof. Justus Hofmeyr, justhof@gmail.com

Contact information

Type(s)
Principal investigator, Public, Scientific

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South African National Clinical Trials Registry (SANCTR)
DOH-27-052026-6525

UKRI MRC Grant Number
MR/Y503423/1

Study information

Scientific Title
Novel extended balloon labour induction/augmentation (EBLIA) device to improve safety of labour induction: preliminary clinical study

Acronym
EBLIA

Study objectives
Several large randomized trials have shown that balloon catheters have similar caesarean birth rates compared with vaginal prostaglandins, less uterine hyperstimulation and fewer adverse perinatal events. Based on evidence of safety, effectiveness and acceptability, wider use of Foley catheter induction of labour has been advocated.

To date the use of balloons has been limited to labour induction with an ‘unfavourable’ cervix able to retain the currently available balloon devices. We have introduced the novel concept of ‘extended balloon labour induction/augmentation’ (EBLIA) with modified balloons to avoid the risks inherent in medical uterine stimulants when the cervix is too dilated to retain a conventional balloon. We have demonstrated ‘proof of concept’ in simulation and clinical studies using two or three Foley balloons side by side. The next step is to test a purpose-designed EBLIA balloon, utilising a ring formation to increase the diameter without increasing the height. The EBLIA balloon is uniquely designed to enable mechanical labour induction with a cervix too dilated to retain currently available balloons.

The current study objectives are ‘proof of principle' by showing that:
1. The device can be used as intended
2. It is acceptable to patients and staff
3. It successfully induces labour

Ethics approval required
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Ethics approval(s)
1. Approved 30/03/2026, Walter Sisulu University Health Research Ethics Committee (Walter Sisulu University, Nelson Mandela Drive, Mthatha, 5117, South Africa; +27 (0)47502210; fhsrec@wsu.ac.za), ref: WSU HREC 459/2025

2. Approved 07/04/2026, South African Health Products Regulation Authority (Building A, Loftus Park, 402 Kirkness Street, Arcadia, Pretoria, 0083, South Africa; +27 (0)125010300; enquiries@sahpra.org.za), ref: MD20260301

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Pregnant participants due for labour induction

Interventions
Preliminary proof-of-concept clinical trial:
The initial trial is designed to assess essential safety, performance, feasibility and acceptability and to give an indication of effectiveness and suitability for a substantive randomized effectiveness trial. It will include a small number of low-risk participants (n = 30). As a benchmark against which to judge the outcomes and to establish the feasibility of a future formal randomized trial, a randomly allocated ‘usual care’ control group will be included (Foley catheter balloon labour induction). In view of the small numbers, formal statistical comparisons will not be performed. Following the required ethical and regulatory approvals, participants who meet the inclusion criteria and consent to participate will be allocated by randomly ordered opaque sealed envelopes to undergo labour induction using the EBLIA balloon or the standard Foley balloon. Allocation will be in a computer-generated random sequence in variable balanced blocks of 4-6 concealed in consecutively numbered opaque sealed envelopes. Participants will receive routine monitoring and care and will be followed up until discharge from hospital. Participants and providers will complete structured and open-ended questionnaires to document acceptability, ease of the procedure, discomfort, and satisfaction. Baseline demography and clinical data will be recorded.

EBLIA procedure:
Participants will be fully counselled about the procedure.
Sterile procedures will be followed as for routine labour induction with a Foley catheter balloon. The EBLIA balloon will be inserted transcervically. The uterine balloon will be inflated with

sterile saline from an infusion set 1.3 m above the participant (100 mmHg). The cervical balloon will be inflated with an infusion set gradually raised to a level which does not cause participant discomfort (0-50 mmHg).

Control:
For the control group, routine Foley labour induction will be performed according to hospital policies.

The fetus and participant will be monitored according to routine hospital labour induction protocols. If not expelled, the balloon will be removed after 48 hours. After expulsion or removal, further care will be according to routine hospital policies.

Data collection:
Data will be collected onto a clinical record form (CRF)

Data management, documentation and curation:
Data will be entered onto an Excel spreadsheet, manually checked for accuracy, and analysed using EpiInfo software. Categorical data will be presented as proportions (%) with 95% confidence intervals. Continuous data will be presented as means (standard deviation) if normally distributed or medians (interquartile range).

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
EBLIA balloon

Primary outcome(s)
1. Established labour (cervical dilation 5 cm or more) within 48 hours without use of amniotomy or uterine stimulants measured using clinical assessment of uterine contractions and cervical dilation in cm at during routine labour assessments

Key secondary outcome(s)
1. Mode of birth measured using clinical assessment at birth

2. Vaginal birth without use of uterine stimulants or amniotomy measured using clinical assessment at birth

3. Fetal heart rate parameters measured using cardiotocography at during labour

4. Uterine hyper-stimulation (5 or more contractions per 10 minutes) measured using cardiotocography at during labour

5. 5-minute Apgar score <7 measured using clinical assessment at 5 minutes after birth

6. Maternal complications measured using clinical assessment at hospital discharge

7. Usability and acceptability to staff and participants measured using structured and semi-structured questionnaires at postpartum

Completion date
30/10/2026

Eligibility

Key inclusion criteria
1. Age >18 years
2. Planned labour induction
3. Singleton cephalic pregnancy
4. Gestation 36 weeks or more
5. Suitable for balloon labour induction
6. Informed consent

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Total final enrolment
60

Key exclusion criteria
Major medical complications such as cardiac disease, diabetes, severe pre-eclampsia

Date of first enrolment
04/06/2026

Date of final enrolment
18/09/2026

Locations

Countries of recruitment
South Africa

Study participating centre
Frere Maternity Hospital
Amalinda Main Road
East London
South Africa
5217

Study participating centre
Cecilia Makiwane Hospital
Billie Road, Mdantsane
East London
South Africa
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Sponsor information

Organisation
Wits Health Consortium, University of the Witwatersrand

Funder(s)

Funder type

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

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

Available on request