ISRCTN14479515 https://doi.org/10.1186/ISRCTN14479515

Postpartum vaginal blood loss following two different methods of cervical ripening

Submission date
23/09/2017

Recruitment status
No longer recruiting

Registration date
16/10/2017

Overall study status
Completed

Last Edited
25/11/2020

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Labour induction is the process or treatment that stimulates childbirth and delivery. It is a common procedure and remains an obstetric challenge. The outcome of induction of labour is very important in a setting where women are prone to chronic anaemia in pregnancy and the adverse effects of heavy blood loss following childbirth. The aim of this study is to compare the outcomes of two different methods of inducing labour that are currently being used in the hospital.

Who can participate?
Pregnant women undergoing induction of labour at the University of Calabar Teaching Hospital

What does the study involve?
Participants are randomly allocated into two groups to have labour induced with either the drug misoprostol or a catheter (tube) inserted into the cervix. Vaginal blood loss is collected using a plastic bag and perineal pad for up to 6 hours after the birth. The time between the start of the intervention and when the baby is delivered is also measured, the wellness of the baby is assessed at 1 minute and 5 minute after delivery, and the acidity of the baby's blood is measured at time of cord clamping.

What are the possible benefits and risks of participating?
Benefits of participation in this study include having all investigations done at no cost and all subsequent treatment (except for Caesarean deliveries) paid for by the researcher. The risks include a possible reaction to the medication being used, risk of infection with insertion of the catheter, and risk of operative vaginal or Caesarean delivery.

Where is the study run from?
University of Calabar Teaching Hospital (Nigeria)

When is the study starting and how long is it expected to run for?
May 2013 to June 2014

Who is funding the study?
University of Calabar Teaching Hospital (Nigeria)

Who is the main contact?
Dr Okon Asuquo Okon
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PACTR201702002017237

Study information

Scientific Title
Postpartum vaginal blood loss following two different methods of cervical ripening: a randomised controlled trial

Study objectives
Induction of labor is a common procedure, and it remains an obstetric challenge. The outcome of induction of labor and its various determinants are paramount in a setting where women are prone to chronic anemia in pregnancy and the adverse effects of heavy blood loss following child birth. The study was designed to determine the postpartum outcome of two different methods of cervical ripening for induction of labor which are currently being used in the hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health Research and Ethics Committee of UCTH, 07/10/2013, ref: UCTH/HREC/33/104

Study design
Single-center randomised open-label trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Induction of labor

Interventions
The different groups receive different interventions at the same time during study, and allocation to either intervention group was randomised. Allocation sequence was generated by simple randomization using a randomization table created by a computer software program. The allocation sequence/code was concealed from the person allocating the participants to the intervention arms using sealed opaque envelopes. Masking: open-label (masking was not used)

Control group: Foley catheter, single insertion into the intra-cervical extra-amniotic space and left in-situ until the catheter was spontaneously expelled, at less than but not greater than 12 hours duration
Experimental group: Vaginal misoprostol, 50 microgram inserted into the posterior vaginal fornix 6 hourly and stopped when the participant was having adequate uterine contractions or to a maximum of 4 doses under 24 hours

Once the fetal head had crowned, a plastic bag was placed under the patient to collect the blood and hind water following the delivery of the fetus and the placenta. It did not require sterilization and was used in the dorsal, lateral, or lithotomy positions. The bag was left in situ until the birth attendant was no longer concerned about blood loss, such as when a sanitary towel was applied to the vulva. Thereafter the collected blood was poured into a graduated measuring cup, promptly read and recorded. The sanitary towel was left in place to collect blood lost per vagina until 6 hours postpartum and then weighed to determine the amount of blood lost. For women undergoing caesarean section the use of suction tubes and bottles and

weighing of the abdominal mops, gauze and swabs was used to determine the amount of blood lost.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Misoprostol

Primary outcome measure
Postpartum vaginal blood loss, measured by collecting blood using an under buttocks plastic collection bag and by perineal pad from the crowning of the fetal head (second stage of labor) up to 6 hours post delivery

Secondary outcome measures
1. Induction delivery interval, measured from the start of intervention to time of childbirth
2. Wellness of the baby, assessed using the Apgar score score at 1 minute and 5 minute post delivery
3. Neonatal cord blood pH at time of cord clamping following delivery of the baby

Overall study start date
01/05/2013

Completion date
14/06/2014

Eligibility

Key inclusion criteria
1. 37 completed weeks up to 41 completed weeks plus 3 days
2. Bishop score of <5
3. A live singleton fetus with cephalic presentation at term with intact membranes with no evidence of labor
4. No contraindications to a vaginal delivery
5. Up to the third parity

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
80

Total final enrolment
80

Key exclusion criteria
1. History of uterine scar
2. Twins
3. Breech presentation
4. Fetal anomalies
5. Antepartum hemorrhage
6. Polyhydramnios
7. Presence of uterine fibroids in pregnancy
8. Known allergy to prostaglandin preparations
9. Women with anemia (defined as hemoglobin level less than 10.5g/dl or a hematocrit of less than 31%)
10. History of bleeding disorders
11. Pelvic abnormalities/deformities

Date of first enrolment
30/04/2014

Date of final enrolment
01/05/2014

Locations

Countries of recruitment
Nigeria

Study participating centre
University of Calabar Teaching Hospital
Unical Hotel road off Etagbo road
Calabar Municipality
Nigeria
540001

Sponsor information

Organisation
University of Calabar Teaching Hospital

Sponsor details
Department of Obstetrics and Gynecology
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Sponsor type
Hospital/treatment centre

Website
http://ucth-ng.net/

ROR
https://ror.org/05qderh61

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University of Calabar Teaching Hospital

Results and Publications

Publication and dissemination plan
Planned publication of the findings online as an open access article, available to medical and paramedical personnel who may find themselves working in countries where patients who may have chronic anemia (such as sickle cell disease patients) go into labor unprepared and in whom even minor blood loss may have a significant impact on their hemo-dynamic system.

Intention to publish date
26/10/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Okon Asuquo Okon (konie9ja@gmail.com). Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices) will be shared from 1 month following publication with no end date. Anyone who wishes to access the data for any purpose. To gain access,
data requestors may need to send a data access agreement. Informed consent was obtained from all participants and anonymity ensured using only the randomization numbers that they picked from the bag containing the randomly generated numbers to identify them on the data sheet.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2017	25/11/2020	Yes	No