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A study to compare the effectiveness of intravenous oxytocin with intramuscular oxytocin given at the third stage of labour at preventing bleeding at vaginal birth

Submission date
14/12/2015

Recruitment status
No longer recruiting

Registration date
04/01/2016

Overall study status
Completed

Last Edited
20/03/2019

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Vaginal birth (delivery of a baby through the vagina without medical assistance) is the natural way for a baby to be born. This type of childbirth is made up of three distinct stages. The first is where the body prepares for the birth (contractions cause the cervix to dilate), the second is where the baby is actually born (passing through the cervix and out of the body) and the third is where the placenta (the organ which connects the mother's blood supply to the baby's via the umbilical cord, providing the baby with food and oxygen) is delivered. During the third stage of labour, bleeding is not uncommon and so medical teams often actively manage this stage to prevent a woman from losing too much blood. After the baby is born, a hormone called oxytocin acts to keep the contractions going so that the placenta can be delivered and any blood vessels attached to it can be closed off, preventing excessive bleeding (postpartum haemorrhage). By giving the woman an injection containing artificial oxytocin, it can help speed up the delivery of the placenta and prevent excess bleeding. This injection can be given a number of ways, such as directly into the bloodstream or into muscle, however it is not known which is the most effective. The aim of this study is to find out the most effective technique of giving oxytocin to women in labour to prevent bleeding.

Who can participate?
Women who have been pregnant for more than 36 weeks with one baby, who are expected to have a vaginal delivery.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in both groups receive two injections (the drug and a dummy) in order to ensure that the way the drug is given is kept secret. Participants in the first group receive an intramuscular injection (injection directly into the muscle) of 1ml oxytocin, and a dummy (placebo) intravenous injection (injection directly into a vein) of 1ml normal saline (salt water). Participants in the second group receive an intravenous injection of 1ml oxytocin and a placebo injection of 1ml normal saline. Following delivery, all

participants' medical notes are reviewed in order to find out how many experienced postpartum haemorrhage. Participants in both groups also have a blood sample taken before delivery and 24 hours after delivery in order to measure any changes in the amount of haemoglobin (iron-containing oxygen-carrying part of red blood cells).

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Coombe Women and Infants University Hospital (Ireland)

When is the study starting and how long is it expected to run for?
January 2012 to October 2017

Who is funding the study?
1. Trinity College Dublin (Ireland)
2. Coombe Women and Infants University Hospital (Ireland)

Who is the main contact?
Dr Francesco Pagnini

Contact information

Type(s)
Scientific

Contact name
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Public

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Additional identifiers

EudraCT/CTIS number
2012-003352-36

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
012012

Study information

Scientific Title
Intramuscular oxytocin versus intravenous oxytocin to prevent haemorrhage at vaginal delivery - A randomised controlled trial

Acronym
LabOR Trial (Labour Oxytocin Randomised Trial)

Study objectives
Intravenous oxytocin used at vaginal delivery will reduce the risk of postpartum haemorrhage compared to intramuscular oxytocin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Committee of National Maternity Hospital, 29/06/2015
2. Research Ethics Committee of Commbe Women and Infants University Hospital, 30/10/2015, ref: 26-2015

Study design
Single-centre double-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Postpartum haemorrhage following vaginal delivery

Interventions
Participants will be randomised into one of two study arms:

Arm one: Participants will receive 1ml 10IU oxytocin intramuscularly and 1ml 0.9% normal saline as placebo intravenously immediately after the delivery of the baby and before the delivery of the placenta at vaginal delivery.

Arm two: Participants will receive 1ml 10IU oxytocin intravenously and 1ml 0.9% normal saline as placebo intramuscularly immediately after the delivery of the baby and before the delivery of the placenta at vaginal delivery.

The blood loss following normal vaginal delivery will be measured using gravimetric method. The blood loss would be estimated by weighing all the soiled materials on a scale and subtracting the known weights of these materials to determine the blood loss. For women who have an assisted vaginal delivery, Comfy Guard ® (a surgical drape with a pouch for collecting vaginal blood loss) will be placed under the woman's buttocks in preparation for birth and before delivery of the placenta. The blood collected in the drape will be transferred to a measuring jar with calibrations. Blood-soaked swabs and drapes will be weighed and the known dry weight of the swabs and drapes will be subtracted. This volume will be added to the measured blood volume from the drape.The measured blood loss is recorded in the participant's medical notes by the attending midwife. Maternal vital signs will be measured after delivery and before transfer to the postnatal ward, which are recorded in the medical notes. The occurrence of side effects will be recorded using an observation form.

Follow-up: A full blood count will be performed at day 1 after delivery to assess haemoglobin and haematocrit. Data will be collected in duplicate on a case report form (CRF) by reviewing patient's/participant's medical notes after the delivery and prior to discharge from the hospital.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Incidence of primary postpartum haemorrhage (> 500ml) following intramuscular oxytocin compared with intravenous oxytocin is determined by reviewing participant's medical notes and data collected in a case report form (CRF) 24 hours post-delivery.

Secondary outcome measures
1. Incidence of side effects following administration of oxytocin (headache, vomiting) is determined by reviewing an observation sheet that the attending midwife are required to fill

within 30 minutes of delivery and oxytocin administration. The vital signs which are taken after delivery and prior to transfer to the postnatal ward are recorded in the medical notes. Occurrence of hypotension, tachycardia are recorded in the CRF by reviewing the medical notes.
2. Estimated mean blood loss and early lochial loss is determined by reviewing participant's medical notes
3. Incidence of major obstetric haemorrhage (measured blood loss ≥ 1000ml) is determined by reviewing participant's medical notes 24 hours post-delivery
4. Objective change in haemoglobin and haematocrit is measured using a full blood count before delivery and 24 hours after delivery
5. Incidence of severe anaemia (Hb fall ≥ 20%) is measured using a full blood count before delivery and 24 hours after delivery
6. Need for blood transfusion and/or blood products is determined by reviewing the participant' s medical notes 24 hours post-delivery
7. Postnatal length of stay in labour ward/HDU and in the hospital is determined by reviewing participant's medical notes
8. Need for an additional uterotonic agent between the two groups is determined by reviewing the participant's medical notes 24 hours post-delivery

Overall study start date
01/01/2012

Completion date
30/01/2018

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Female participants only
3. Singleton pregnancy at more than 36 weeks gestation
4. Those anticipated to have a vaginal delivery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
A total of 1000 participants. 500 in each arm

Key exclusion criteria
1. Women who opted for physiological management of the third stage of labour
2. Those who have an antenatal decision for 40IU oxytocin infusion prophylactically following a

vaginal delivery
3. Those whom the clinician has a preferred route of administering prophylactic oxytocin for the third stage of labour
4. Those who are deemed to be at risk of postpartum haemorrhage - Previous history of atonic primary postpartum haemorrhage, multiple fibroids, coagulation disorders, thrombocytopenia and receiving anticoagulants
5. Those with previous cardiovascular disorder

Date of first enrolment
04/01/2016

Date of final enrolment
13/12/2017

Locations

Countries of recruitment
Ireland

Study participating centre
Coombe Women and Infants University Hospital
Dolphins Barn
Dublin
Ireland
Dublin 8

Sponsor information

Organisation
Coombe Women and Infants University Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00bx71042

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Trinity College Dublin

Alternative Name(s)
Coláiste na Tríonóide, Baile Átha Cliath, TCD

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Funder Name
The Coombe Women and Infants University Hospital

Results and Publications

Publication and dissemination plan
Planned dissemination of results through a final report prepared for the funding body and manuscripts submitted for publication in peer reviewed journals.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/11/2017		Yes	No
Results article	results	04/09/2018	20/03/2019	Yes	No