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The Release Trial: a randomised trial of umbilical vein oxytocin versus placebo for the treatment of retained placenta.

Submission date 13/09/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/10/2004	**Overall study status** Completed	
Last Edited 18/12/2009	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.releasestudy.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LWH 0481

Study information

Scientific Title

Acronym
RELEASE

Study objectives
The injection of oxytocin down the umbilical vein has been proposed as a treatment for retained placenta. It can be performed by midwives in health centres and needs only the drug and a syringe. Its efficacy has been tested in a number of randomised trials with varying results. A recent meta-analysis by the Cochrane collaboration suggests that it is of borderline efficacy. However, the previous trials have used a wide variety of oxytocin doses as well as a method of injection that has been shown to deliver little of the oxytocin to the placental bed. The results of a recent observational study suggests that with higher oxytocin doses delivered through a tube passed up the umbilical vein, high success rates can be obtained. The results of a pilot study of 10 women, suggests that a dose of 50 IU in 30 ml saline may be effective at delivering the placenta.

A multi-centre randomised trial of this new method of umbilical vein injection is proposed. It will involve 572 women of over 34 weeks gestation with retained placenta of at least 30 minutes duration. The study centres will initially be Mulago Hospital, Kampala, Liverpool Women's Hospital, Liverpool and the Jessop Wing, Sheffield. The trial will be double-blind and women with retained placenta who are not bleeding excessively will be randomised to receive either oxytocin (50 IU in 30 ml saline) or placebo. Women will be eligible for inclusion from 30 minutes post-delivery and the primary outcome measure will be the incidence of manual removal of placenta. Women will go for immediate manual removal if haemorrhage occurs or at 30 minutes following the oxytocin injection. A study involving 572 women will have 80% power to detect a 20% reduction in the relative risk of manual removal with 95% significance.

The hypothesis is that intra-umbilical injection of oxytocin reduces the incidence of manual removal compared with placebo in the treatment of retained placenta.

Please note that as of 14/09/2007 the details of this trial were updated by the Principal Investigator (see contact details). Most changes are noted with the date 14/09/2007. The following amendment has also been made:

Pakistan has been added to the list of countries of recruitment as of 14/09/2007

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Ethical approval was granted for the RELEASE trial on 24th June 2004 by the London Multi-Centre Research Ethics Committee (reference MREC/03/2/075).
2. Local ethical approval has also been granted by the Pakistan and Uganda institutions involved.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Retained Placenta

Interventions
Either 50 IU oxytocin or sterile water in 25 ml saline injected into the umbilical vein.

Please note the previous anticipated end date of this trial was 31/12/2007 (see hypothesis for details of this update).

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Manual removal of the placenta following randomisation

Secondary outcome measures
Drop in haemoglobin, measured blood loss, need for transfusion, need for surgery

Overall study start date
01/12/2004

Completion date
31/05/2008

Eligibility

Key inclusion criteria
1. 600 women with retained placenta for over 30 minutes
2. Written informed consent
3. Estimated gestation at least 34 weeks (or birth weight of 2 kg if gestation unknown)
4. Umbilical cord is clamped and cut
5. In the UK participants should be over 18 years of age, or over 16 and Gillick competent
6. In Uganda participants should be over 18

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
600 (572 as of 14/09/2007)

Key exclusion criteria
1. Vaginal bleeding or maternal haemodynamic instability (Pulse >100 bpm or systolic blood pressure <100 mmHg) necessitating immediate placental removal
2. Torn umbilical cord making catheterisation impossible
3. Completely physiological third stage management (no cord cutting or clamping, no prophylactic oxytocics, no cord traction or fundal pressure)
4. Stillborn baby

Date of first enrolment
01/12/2004

Date of final enrolment
31/05/2008

Locations

Countries of recruitment
England

Pakistan

Uganda

United Kingdom

Study participating centre
Department of Obstetrics and Gynaecology
Liverpool
United Kingdom
L8 7SS

Sponsor information

Organisation
Liverpool Women's Hospital (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.lwh.org.uk/

ROR
https://ror.org/00eysw063

Funder(s)

Funder type
Research organisation

Funder Name
WellBeing (UK) (ref: W1/03)

Funder Name
United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA) /World Health Organization (WHO)/World Bank - Special Programme of Research, Development and Research Training in Human Reproduction (HRP) - Ugandan part of the trial (ref: A35026)

Funder Name
Higher Education Commission of Pakistan (Pakistan) - funding for the Pakistan arm of the trial (added 14/09/2007)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/10/2005		Yes	No
Other publications	experiences and lessons for gaining informed consent	11/05/2006		Yes	No
Results article	results	09/01/2010		Yes	No