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European project on obstetric haemorrhage reduction: attitudes, trial, and early warning system

Submission date
06/09/2005

Recruitment status
No longer recruiting

Registration date
05/01/2006

Overall study status
Completed

Last Edited
25/02/2010

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Sophie Alexander

Contact details
CP 597
808, Route de Lennik
Brussels
Belgium
1070
+32 25554079
salexand@ulb.ac.be

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
EUPHRATES

Study objectives
The objective of this trial is to test the effectiveness of the routine use of a collector bag in the third stage of labour. The hypothesis is that enhanced visual awareness of blood loss will induce more timely management, specifically when bleeding is excessive but before haemorrhage has become catastrophic, leading to a decrease in the incidence of severe post-partum haemorrhage. Our null hypotheses is that using a collector bag will be no more effective than visual estimated in accurate measurement of blood loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval was obtained in each country from relevant local or national research ethics committees

Study design
Randomised Controlled Trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Severe post-partum haemorrhage

Interventions
A collector bag, placed under the pelvis (buttocks) of each woman just after birth.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
The primary outcome is a composite marker of severe post-partum haemorrhage. This includes all women who experience one or more of the following:
1. Death from post-partum haemorrhage
2. Blood transfusion
3. Receipt of an intravenous plasma expander in the post-partum period
4. Admission to intensive care because of post-partum haemorrhage
5. Embolisation or surgical procedures for post-partum haemorrhage, such as emergency hysterectomy
6. Treatment with recombinant factor VII (Novo7)

Secondary outcome measures
1. Each of the components of the primary outcome
2. Post-delivery haemoglobin (Note: these data will only be available from units where haemoglobin is routinely measured at two to three days after delivery)
3. Manual removal of placenta
4. Use of prostaglandins
5. Maternal death

Overall study start date
01/10/2005

Completion date
30/09/2006

Eligibility

Key inclusion criteria
Maternity units in 14 countries; To ensure that the standard of care for management of the third stage of labour is similar across all participating units, the maternity units in each country will be required to comply with the EUPHRATES consensus statement on the prevention and management of post-partum haemorrhage. If centres are already using collector sacs routinely in the third stage of labour, they will be eligible to participate only if they are willing to stop using the sacs if they are randomised to that group.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
82

Key exclusion criteria

Maternity units with less than 400 births per year or unable to collect outcome data

Date of first enrolment
01/10/2005

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
Belgium

Study participating centre
CP 597
Brussels
Belgium
1070

Sponsor information

Organisation
European Union DG Research

Sponsor details
Square de Meeus
SDME 7/20
Brussels
Belgium
1049
+32 22955873
Veronique.Bernard@cec.eu.int

Sponsor type
Other

Website
http://www.cordis.lu

ROR
https://ror.org/019w4f821

Funder(s)

Funder type
Other

Funder Name
European Union (EU) (ref: QLG4-CT-2001-01352)

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?
Results article	results	01/02/2010		Yes	No