ISRCTN40302163 https://doi.org/10.1186/ISRCTN40302163

A randomised controlled trial of oxytocin 5 IU versus oxytocin 5 IU and 30 IU infusion for the control of blood loss at elective caesarean section: a pilot study

Submission date
28/09/2006

Recruitment status
No longer recruiting

Registration date
13/04/2007

Overall study status
Completed

Last Edited
03/05/2011

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
Dr Graeme McLeod

Contact details
University Department of Anaesthesia
Ninewells Hospital and Medical School
Dundee
United Kingdom
DD1 9SY

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2004OB04

Study information

Scientific Title

Study objectives
A study to investigate the alternative uses of oxytocin at elective caesarean section and its effect on maternal blood loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethics Committee for Scotland B, Edinburgh in March 2005 (ref: 05/MRE10/20)

Study design
Double blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Study of blood loss associated with different use of syntocinon

Interventions
Women randomly allocated to receive syntocinon 5 IU or syntocinon 5 IU and 30 IU infusion at the time of elective caesarean section using standardised anaesthetic and surgical procedures.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure

The primary outcome measure is estimated blood loss at caesarean section.

Secondary outcome measures
1. Change in haemoglobin and haematocrit
2. Need for additional uterotonic agents
3. Incidence of major obstetric haemorrhage
4. Need for blood transfusion, side effects and length of sat in the labour ward

Overall study start date
29/08/2005

Completion date
28/09/2006

Eligibility

Key inclusion criteria
Pregnant women choosing to have elective caesarean section at term in a healthy low risk pregnancy.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
120

Key exclusion criteria
1. Women who do not understand English
2. Have a pregnancy complicated by thrombocytopenia
3. Coagulopathy or anti-coagulant therapy
4. Are expecting a multiple birth

Date of first enrolment
29/08/2005

Date of final enrolment
28/09/2006

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University Department of Anaesthesia
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
NHS Tayside (UK)

Sponsor details
c/o Professor J Stewart Forsyth
Ninewells Hospital and Medical School
Medical Director's Office
Single Divisional Unit
Level 10
Dundee
Scotland
United Kingdom
DD1 9SY

Sponsor type
Hospital/treatment centre

Website
http://www.nhstayside.scot.nhs.uk/

ROR
https://ror.org/000ywep40

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (UK) (reference: CGZ/2/185)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
Obstetric Anaesthetists Association (UK)

Alternative Name(s)
OAA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
Tenovus (UK)

Alternative Name(s)
Tenovus Cancer Care

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Anonymous Trust

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	01/01/2009		Yes	No