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
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University Department of Anaesthesia
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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

Scotland

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

Sponsor information

Organisation
NHS Tayside (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)
The Obstetric Anaesthetists' Association (OAA), The OAA, The Obstetric Anaesthetists' Association, OAA

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Tenovus (UK)

Alternative Name(s)

Tenovus Cancer Care

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Anonymous Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2009		Yes	No