

A randomised controlled trial of oxytocin bolus versus oxytocin bolus and infusion for the control of blood loss at elective caesarean section

Submission date 10/12/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 25/03/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/08/2019	Condition category Signs and Symptoms	☐ 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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Additional identifiers

Clinical Trials Information System (CTIS)

2006-004799-11

Protocol serial number

EudraCT number

Study information

Scientific Title

A multi-centre randomised controlled trial of oxytocin 5 IU bolus and placebo infusion versus oxytocin 5 IU bolus and 40 IU infusion for the control of blood loss at elective caesarean section

Acronym

ECSSIT - Elective Caesarean Section Syntocinon Infusion Trial

Study objectives

The hypothesis is that an oxytocin infusion used in addition to an oxytocin bolus at elective caesarean section will reduce the risk of major haemorrhage and anaemia.

Please note that the pilot study to this trial is assigned to 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 (see <http://www.controlled-trials.com/ISRCTN40302163>).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Central Trials Ethics Committee (National Maternity Hospital, Holles Street, Dublin, Ireland) on the 29th November 2007.

Primary study design

Interventional

Study design

Multi-centre double blinded randomised controlled trial.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Study of blood loss at caesarean section associated with different use of oxytocin

Interventions

Patients will be randomised in a double-blind trial to receive either:

1. An intravenous slow bolus of oxytocin (5 IU) and placebo infusion (500 ml 0.9% saline), or
2. An intravenous slow bolus of oxytocin (5 IU) and oxytocin infusion (40 IU in 500 ml 0.9% saline over four hours)

At elective caesarean section. The patients will be followed-up until discharge from the hospital post-natally.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Oxytocin

Primary outcome(s)

To compare:

1. The incidence of major obstetric haemorrhage (greater than or equal to 1000 ml)
2. The need for an additional uterotonic agent

We will define major obstetric haemorrhage in two ways:

1. Estimated blood loss as described by theatre staff
2. Estimated blood loss as calculated from pre- and post-operative haematocrit. The post-operative haematocrit will be measured at 48 hours.

Key secondary outcome(s)

To compare:

1. The estimated mean operative blood loss and early lochial loss
2. The objective change in haemoglobin (Hb) and haematocrit before and 48 hours after delivery
3. The incidence of severe anaemia (Hb fall greater than or equal to 20%) 48 hours after delivery
4. The need for blood transfusion and/or blood products
5. The incidence of side effects
6. The post-natal length of stay on the labour ward and in the hospital

The outcomes will be measured at various timepoints - from the time of the operation to discharge from the hospital. Clinical follow-up of the mother will be completed prior to hospital discharge.

Completion date

31/12/2009

Eligibility

Key inclusion criteria

1. Healthy women
2. Greater than 36 weeks gestation
3. Singleton pregnancies
4. Booked for elective caesarean section

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

2069

Key exclusion criteria

1. Placenta praevia
2. Thrombocytopaenia
3. Coagulopathies
4. Previous major obstetric haemorrhage (greater than 1000 ml)
5. Patients receiving anti-coagulant therapy
6. Non-English speakers
7. Under 18 years of age

Date of first enrolment

01/01/2008

Date of final enrolment

31/12/2009

Locations**Countries of recruitment**

Ireland

Study participating centre

Department of Obstetrics & Gynaecology

Dublin

Ireland

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Sponsor information**Organisation**

Health Research Board of Ireland (Ireland)

ROR

<https://ror.org/003hb2249>

Funder(s)**Funder type**

Government

Funder Name

Health Research Board of Ireland (Ireland) (ref: RP/2007/171)

Results and Publications

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	01/08/2011	21/08/2019	Yes	No
Protocol article	protocol	24/08/2009		Yes	No