

# 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

<b>Submission date</b> 28/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/05/2011	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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  
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## 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 stay 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?
<a href="#">Results article</a>	results	01/01/2009		Yes	No