# 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	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
28/09/2006		☐ Protocol		
Registration date 13/04/2007	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
03/05/2011	Pregnancy and Childbirth			

# 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

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