# Oxytocin augmentation vs conservative management for primary dysfunctional labour in nulliparous women: a randomised, controlled trial.

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
23/01/2004		☐ Protocol		
Registration date 23/01/2004	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
03/12/2008	Pregnancy and Childbirth			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

### Contact name

Dr Kim Hinshaw

### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

# Secondary identifying numbers

MCH 02-17

# Study information

### Scientific Title

# **Study objectives**

The aim of the study is to find out whether oxytocin reduces Caesarean Section Rates to assess its effects on other labour and neonatal outcomes and in particular to assess its effects on maternal perception of pain etc and satisfaction with labour.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Not provided at time of registration

# Study design

Randomised controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Not specified

# Study type(s)

**Not Specified** 

# Participant information sheet

# Health condition(s) or problem(s) studied

Pregnancy and childbirth: Childbirth

### **Interventions**

Not provided at time of registration

# **Intervention Type**

Other

# **Phase**

**Not Specified** 

# Primary outcome measure

A scientific evaluation of a widely introduced but as yet unproven labour intervention. It will look at the health gain in terms of any subsequent psychological dysfunction. The effects of the different interventions on the Caesarean Section Rates is another primary outcome measure. Any reduction in the Caesarean Section Rate is likely to have economic benefit to the NHS in terms of cost reduction.

# Secondary outcome measures

Not provided at time of registration

# Overall study start date

01/08/1998

# Completion date

01/02/2002

# Eligibility

# Key inclusion criteria

Women in spontaneous labour in their first pregnancy at term (37-42 weeks). There must be a singleton vertex presentation with no significant antenatal or intrapartum problems.

# Participant type(s)

**Patient** 

# Age group

Adult

### Sex

Female

# Target number of participants

Added December 2008: 412

# Key exclusion criteria

Not provided at time of registration

### Date of first enrolment

01/08/1998

# Date of final enrolment

01/02/2002

# Locations

# Countries of recruitment

England

United Kingdom

Study participating centre
Obstetrics and Gynaecology
Sunderland
United Kingdom
SR4 7TP

# Sponsor information

# Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

# Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL

# Sponsor type

Government

### Website

http://www.doh.gov.uk

# Funder(s)

# Funder type

Government

### **Funder Name**

NHS Mother and Child Health National Research and Development Programme (UK)

# **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	01/09/2008		Yes	No