ISRCTN78205641 https://doi.org/10.1186/ISRCTN78205641

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

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
03/12/2008

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

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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