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A randomised controlled trial of amniotomy and immediate oxytocin infusion versus amniotomy and delayed oxytocin infusion for induction of labour at term

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
28/09/2011

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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0270181703

Study information

Scientific Title

Study objectives
The aim of this study is to compare the efficacy of amniotomy (breaking baby's bag of waters) and immediate syntocinon (oxytocin) infusion with amniotomy and delayed syntocinon infusion in induction of labour at term.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 8 September 2008: Barnet, Enfield & Haringey Local Ethics Committee (UK), 20/01/2006, Ref Number 05/Q0509/65.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Pregnancy and Childbirth: Labour induction

Interventions
Amniotomy and immediate oxytocin infusion versus amniotomy and delayed oxytocin

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
oxytocin

Primary outcome measure
The proportion of women in active labour after 4 hours and over the course of time

Secondary outcome measures
Added 8 September 2008:
1. Mode of delivery
2. Need for epidural analgesia
3. Incidence of uterine hyperstimulation
4. Abnormal fetal heart recordings (by CTG)
5. 5-minute Apgar score < 7
6. Umbilical arterial cord pH < 7.2
7. Admission to neonatal intensive care unit
8. Womens satisfaction

Overall study start date
09/01/2005

Completion date
03/01/2006

Eligibility

Key inclusion criteria
Women that will be invited to take part in the study will be drawn from the antenatal clinic. These women will be identified during routine antenatal clinic sessions. They will be women in their first pregnancy who have past their delivery dates and are thus planned for routine induction of labour. Interested patients will be given the patient information leaflet to take home.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
112

Key exclusion criteria
Added 8 September 2008:

Women who decline to participate or with:
1. Preterm pregnancies
2. Multiple pregnancies
3. Regular uterine contractions (≥1 in 10 minutes)
4. Abnormal pre-induction fetal heart rate trace
5. Rupture of membranes
6. Significant fetal or maternal medical condition
7. Previous uterine surgery

Date of first enrolment
09/01/2005

Date of final enrolment
03/01/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Consultant Obstretrician and Gynaecologist
Enfield
United Kingdom
EN2 8JL

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Barnet and Chase Farm Hospitals NHS Trust (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	01/06/2009		Yes	No