

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	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/09/2011	Condition category 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

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Contact details

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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 Obstetrician 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

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