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High or Low Dose Syntocinon (Oxytocin) for delay in labour

Submission date	Recruitment status	[X] Prospectively registered
29/10/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/05/2020	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.holds.bham.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2009-012752-24

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8896

Study information

Scientific Title
High or Low Dose Syntocinon (Oxytocin) for delay in labour

Acronym
HOLDS

Study objectives
Use of high dose oxytocin will achieve more effective uterine contractions resulting not only in shorter labours but in a higher chance of vaginal birth in women who are diagnosed as having delay in the first stage of labour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
23/06/2010 (ref: 10/H0406/30)

Study design
Multicentre randomised interventional treatment trial with an observational qualitative element

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Reproductive Health and Childb; Subtopic: Reproductive Health and Childb (all Subtopics); Disease: Reproductive Health & Childbirth

Interventions
Syntocinon, 10 IU versus 20 IU

Study entry: single randomisation only

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Syntocinon (Oxytocin)

Primary outcome measure
Birth and early postnatal period

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2010

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. Consenting nulliparous women with a singleton pregnancy at term (37 - 42 weeks) gestation
2. Confirmed delay in labour as defined by NICE Intrapartum Care Guideline and with ruptured membranes
3. Labour is established when there are regular painful contractions and progressive cervical dilation from 4 cm. Delay is suspected when cervical dilatation of less than 2 cm in 4 hours occurs once labour is established. Delay is confirmed when progress of less than 1 cm in 2 hours is found on repeat vaginal examination.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned sample size: 100; UK sample size: 100

Total final enrolment
94

Key exclusion criteria
1. Under 16 years old
2. Induction
3. Body mass index (BMI) greater than 40
4. Multiple pregnancy
5. Existing maternal or fetal disease or concern

6. Gestational diabetes
7. Previous uterine surgery
8. Vaginal bleeding in this pregnancy of clinical significance
9. Contra-indication to oxytocin therapy

Date of first enrolment
01/11/2010

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Public Health and Epidemiology
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Department of Public Health and Epidemiology
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
University/education

Website
http://www.staff.bham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

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?
Basic results			28/05/2020	No	No
HRA research summary			28/06/2023	No	No