

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

Submission date 29/10/2010	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 29/10/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/05/2020	Condition category Pregnancy and Childbirth	☐ 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

Clinical Trials Information System (CTIS)
2009-012752-24

Protocol serial number
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

Study type(s)

Treatment

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(s)

Birth and early postnatal period

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

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

Sponsor information

Organisation
University of Birmingham (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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes