

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

<b>Submission date</b> 29/10/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/05/2020	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

**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?
<a href="#">Basic results</a>			28/05/2020	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No