Immediate versus Delayed Oxytocin Following Amniotomy for labour induction

Submission date 13/11/2009	Recruitment status No longer recruiting
Registration date 11/12/2009	Overall study status Completed
Last Edited 28/01/2013	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

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 733.18

Study information

Scientific Title

Immediate versus Delayed Oxytocin Following Amniotomy for labour induction in parous women with favourable cervixes: a double blind randomised controlled trial

Acronym

IDOFA trial

Study objectives

Delayed oxytocin compared with immediate oxytocin will result less use of oxytocin but result in a proportion of vaginal deliveries achieved within 12 hours and patient satisfaction.

Ethics approval required Old ethics approval format

Ethics approval(s) University of Malaya Medical Centre Medical Ethics Committee approved on the 31st July 2009.

Study design Double blind 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

Induction of labour

Interventions

After amniotomy for labour induction:

1. Immediate oxytocin (blinded) starting at 1 mU/min (3 ml/hr, doubling in rate as required every 30 minutes to achieve 3 - 4 uterine contractions every 10 minutes (or to a maximum rate of 16 mU/min (48 ml/hr) if 3 - 4 contractions per 10 minutes not achieved) in the first 4 hours 2. Saline (blinded placebo) infusion with same regime as above

After 4 hours, the woman is reassessed and open label oxytocin started if clinically required and standard labour management applies.

Intervention Type

Drug

Phase Not Applicable

Drug/device/biological/vaccine name(s)

Oxytocin

Primary outcome measure

Vaginal delivery within 12 hours
 Maternal satisfaction score with the birth process (10 point visual numerical rating score VNRS)

Secondary outcome measures

- 1. Induction to delivery interval
- 2. Mode of delivery/caesarean delivery
- 3. Use opiate/epidural analgesia in labour
- 4. Prenatal oxytocin use
- 5. Intrapartum and postpartum fever
- 6. Delivery blood loss
- 7. Maternal antibiotic use
- 8. Induction to hospital discharge interval
- 9. Apgar Score
- 10. Umbilical arterial blood pH
- 11. Neonatal jaundice requiring phototherapy or more
- 12. Neonatal admission

Overall study start date

15/11/2009

Completion date

14/11/2010

Eligibility

Key inclusion criteria

- 1. Females aged over 16 years
- 2. Planned labour induction
- 3. Parous (at least 1 prior vaginal birth greater than 24 weeks)
- 4. Term gestation (greater than 36 weeks)
- 5. Bishop score on recruitment greater than or equal to 6 with cervical dilation greater than or equal to 2 cm suitable for amniotomy
- 6. Intact membranes
- 7. Singleton pregnancy
- 8. Cephalic presentation
- 9. Reassuring cardiotocograph

Participant type(s)

Patient

Age group

Adult

Sex Female

Target number of participants At least 206 women

Key exclusion criteria

1. Previous uterine incision or injury (e.g. caesarean delivery, myomectomy, perforation)

- 2. Gross foetal anomaly
- 3. Contraindication for vaginal birth

Date of first enrolment 15/11/2009

Date of final enrolment 14/11/2010

Locations

Countries of recruitment Malaysia

Study participating centre Dept of Obstetrics & Gynaecology Kuala Lumpur Malaysia 50603

Sponsor information

Organisation University of Malaya (Malaysia)

Sponsor details

University Malaya Medical Centre Department of Obstetrics & Gynaecology Lembah Pantai Kuala Lumpur Malaysia 50603

Sponsor type

University/education

Website http://www.um.edu.my/

ROR https://ror.org/00rzspn62

Funder(s)

Funder type University/education

Funder Name University of Malaya (Malaysia)

Alternative Name(s) University of Malaya, University Malaya, Malayan University, UM

Funding Body Type Government organisation

Funding Body Subtype Universities (academic only)

Location Malaysia

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	01/02/2013		Yes	No