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Immediate versus Delayed Oxytocin Following Amniotomy for labour induction

Submission date 13/11/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/12/2009	**Overall study status** Completed	
Last Edited 28/01/2013	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
1. Vaginal delivery within 12 hours
2. 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
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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