

Immediate versus Delayed Oxytocin Following Amniotomy for labour induction

Submission date 13/11/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/12/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/01/2013	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2013		Yes	No