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Effect of coital activity on onset of labour in women scheduled for labour induction: a randomised controlled trial

Submission date	Recruitment status	[_] Prospectively registered
14/06/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/06/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/10/2014	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
492.7

Study information

Scientific Title

Study objectives
Pregnant women with an appointment for labour induction at term:
1. Will respond to counseling to have vaginal sex as frequently as possible to promote labour onset, and
2. Spontaneous labour onset rate will increase as result

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee University Malaya Medical Centre, 15/03/2005, ref: HU-61/12/1-1

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy: labour induction

Interventions
Counselling to encourage vaginal sex versus no counselling.

Intervention:
1. Counselling by a single investigator (identifiable to women as a doctor) after recruitment
2. Inform women that sexual intercourse is safe and can promote onset of labour
3. Inform women that induced labour is associated with operative delivery and is a more prolonged process compared to spontaneous labour
4. Advise women to have vaginal sex as frequently as possible before their appointment for labour induction to promote labour
5. Ask women to keep a daily diary on vaginal sexual intercourse and any orgasms (marking day when vaginal sex occurs and similarly orgasm if any)

The above intervention/counselling usually takes about 5 to 15 minutes depending on queries. If there are any queries, the response is generally supportive of having sex. The aim is to encourage vaginal sex to promote labour.

Control:
1. Interaction with same investigator
2. Keep session as brief as possible
3. Inform women that sexual intercourse is safe but the effect on labour onset is unclear
4. Ask women to keep diary as above

The above process usually takes about five minutes - most of the time will be on instructions about diary entries. If there are any queries, refer women to standard information leaflet (made available to all trial women - neutral content). The aim is not to influence coital activity in control women.

The intervention comprises of a single counselling session as above. Providers are blind to randomisation. The appointments for labour induction are typically made for within the week ahead. Diaries are collected as soon as possible after delivery. Other outcome measures extracted from clinical notes after delivery. Women who miss their appointment for labour induction are contacted by telephone for information.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Reported coital activity from diary (kept from recruitment to delivery - expected to be only days worth in most instances)
2. Labour onset on or before appointment for labour induction: spontaneous labour (defined as spontaneous uterine contractions resulting in cervical dilatation of at least 3 cm) or pre-labour rupture of membranes on or before appointment date for labour induction

Primary outcomes should typically be resolved within one week of recruitment (no requirement for long term follow up).

Secondary outcome measures
1. Reported orgasms
2. Mode of delivery
3. Recruitment to birth admission interval
4. Initial Bishop Score at the admission for birth
5. Pre-labour rupture of membranes
6. Use of dinoprostone
7. Use of oxytocin infusion during labour
8. Maternal fever
9. Epidural use in labour
10. Meconium stained liquor
11. Delivery blood loss

12. Neonatal admission
13. Apgar score at five minutes
14. Umbilical cord blood pH

Secondary outcomes are events during labour, at delivery or during the usually short hospital confinement after birth. No data is collected after hospital discharge.

Overall study start date
01/12/2005

Completion date
31/08/2007

Eligibility

Key inclusion criteria
Pregnant women:
1. Given an appointment for non urgent labor induction at term
2. Viable foetus
3. Singleton
4. Cephalic presentation
5. Intact membranes

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
209

Key exclusion criteria
1. Previous caesarean section
2. Known gross foetal anomaly

Date of first enrolment
01/12/2005

Date of final enrolment
31/08/2007

Locations

Countries of recruitment
Malaysia

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

Sponsor information

Organisation
University of Malaya Medical Centre (Malaysia)

Sponsor details
Lembah Pantai
Kuala Lumpur
Malaysia
50603

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/00vkrxq08

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	01/10/2007		Yes	No