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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

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
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).

### Key secondary outcome(s))
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.

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### 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)

### 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, 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 | 01/10/2007 | | Yes | No |