

Randomised Controlled Trial of the effect of Advice On Sexual Intercourse after 36 weeks on pregnancy duration and the rate of induction of labour thereafter

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| Submission date 19/08/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 11/09/2007 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 15/03/2013 | 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
N/A

Study information

Scientific Title

Acronym

RCTAOSI

Study objectives

Current evidences suggest that sexual intercourse has a role in promoting labour. All mentioned evidences are based on prospective observational studies and it is unknown at present whether advice on sexual intercourse at 36 weeks would be of value in initiation of labour. Hence, we propose an interventional study: a randomised controlled trial to study the effect of advising or encouraging sexual intercourse after 36 weeks gestation to ascertain the effect of the intervention on the primary outcomes of:

1. Actual frequency of sexual activity
2. Duration of pregnancy
3. Requirement of induction of labour for prolonged pregnancy

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Ethics Committee of University of Malaya Medical Centre on the 16th August 2006 (ref: 523.3).

Study design

Single-centre, single-blind, randomised controlled trial.

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Pregnancy

Interventions

Advice on sexual intercourse versus usual care only.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Duration of pregnancy
2. Rate of induction of labour

Key secondary outcome(s))

1. Hospital admissions since randomisation
2. Length of gestation
3. Prelabour rupture of membranes (PROM)
4. Method of labour induction (if any)
5. Indication for labour induction
6. Length of labour
7. Epidural use in labour
8. Oxytocin augmentation
9. Mode of delivery
10. Indications for operative delivery
11. Endometritis
12. Maternal hospital stay
13. Apgar score
14. Cord pH at birth
15. Admission to the neonatal unit
16. Indication for neonatal admission

Completion date

01/09/2009

Eligibility

Key inclusion criteria

Women attending University Malaya Medical Centre (UMMC) antenatal clinic at 35 weeks gestation will be approached to enter the study. Women who have not been sexually active in the last 6 weeks will be eligible for trial entry.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Placenta praevia
2. Antepartum haemorrhage
3. Ruptured membranes
4. Previous caesarean
5. Hypertension
6. Diabetes
7. Growth restricted baby
8. Multiple gestations
9. Previous stillbirth
10. Foetal anomalies

Date of first enrolment

01/09/2007

Date of final enrolment

01/09/2009

Locations

Countries of recruitment

Malaysia

Study participating centre

B1206 University Towers

Selangor

Malaysia

46200

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 Medical Centre (Malaysia)

Results and Publications

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 |