

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

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

Pregnancy

Interventions

Advice on sexual intercourse versus usual care only.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

01/09/2007

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

Age group

Adult

Sex

Female

Target number of participants

1623

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)

Sponsor details

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sitizawiah@um.edu.my

Sponsor type

University/education

Website

<http://www.um.edu.my>

ROR

<https://ror.org/00vkrxq08>

Funder(s)

Funder type

University/education

Funder Name

University of Malaya Medical Centre (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