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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

Registration date
11/09/2007

Overall study status
Completed

Last Edited
15/03/2013

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
50603
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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