

# 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

<b>Submission date</b> 19/08/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/03/2013	<b>Condition category</b> 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?
<a href="#">Results article</a>	results	01/02/2013		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes