

# Randomised placebo controlled trial of outpatient cervical ripening with isosorbide mononitrate (IMN) prior to induction of labour - clinical trial with analyses of efficacy, cost effectiveness and acceptability

<b>Submission date</b> 13/06/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/03/2020	<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**  
RN04OB007

# Study information

## Scientific Title

Randomised placebo controlled trial of outpatient cervical ripening with isosorbide mononitrate (IMN) prior to induction of labour - clinical trial with analyses of efficacy, cost effectiveness and acceptability

## Acronym

IMOP

## Study objectives

Outpatient isosorbide mononitrate will result in a shorter inpatient stay before delivery, decreased costs to the health service, and greater maternal satisfaction with induction of labour, compared with placebo treatment

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Cervical ripening prior to induction of labour

## Interventions

Isosorbide mononitrate 40 mg (or placebo) given vaginally 48 hours, 32 hours and 16 hours prior to scheduled admission for induction of labour.

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Isosorbide mononitrate (IMN)

## Primary outcome(s)

i. Elapsed time interval from hospital admission to vaginal delivery (defined as the time from admission for inpatient induction or admission in labour to delivery)

- ii. Costs to the health service of induction of labour
- iii. Womens experience of induction of labour

### **Key secondary outcome(s)**

- iv. Operative delivery rates
- v. Incidence of unscheduled admission for reasons other than labour commencing
- vi. Duration and frequency of neonatal admissions to special care
- vii. Incidence of adverse maternal and fetal outcomes such as uterine hypercontractility, postpartum haemorrhage (maternal outcomes) and meconium stained liquor, five minute Apgar of less than seven (fetal outcomes)
- viii. Length of labour
- ix. Oxytocin augmentation rates
- x. Epidural usage
- xi. Proportion with unfavourable cervix at 24 hours after admission
- xii. Requirement for additional inpatient cervical ripening agent

### **Completion date**

31/01/2007

## **Eligibility**

### **Key inclusion criteria**

1. Bishop score less than or equal to 6
2. Singleton pregnancy
3. Nulliparity
4. Gestation greater than or equal to 37 completed weeks
5. Willing to self administer vaginal tablets

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **Key exclusion criteria**

Fetal compromise of sufficient severity such that daily fetal monitoring is scheduled

### **Date of first enrolment**

01/02/2005

### **Date of final enrolment**

31/01/2007

## **Locations**

## Countries of recruitment

United Kingdom

Scotland

## Study participating centre

University of Glasgow Division of Developmental Medicine

Glasgow

United Kingdom

G31 2ER

## Sponsor information

### Organisation

Greater Glasgow Health Board (North Glasgow University Hospitals Division) and The University of Glasgow (UK)

### ROR

<https://ror.org/05kdz4d87>

## Funder(s)

### Funder type

Charity

### Funder Name

Wellbeing (Charity) Ref. CT 2004

## 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	25/07/2006		Yes	No

<a href="#">Results article</a>	results	01/08/2009		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes