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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

Submission date
13/06/2005

Recruitment status
No longer recruiting

Registration date
25/07/2005

Overall study status
Completed

Last Edited
16/03/2020

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

Study website
https://www.charttrials.abdn.ac.uk/imop/index.php

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: https://www.charttrials.abdn.ac.uk/imop/pis.php

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 measure
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

Secondary outcome measures
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

Overall study start date
01/02/2005

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

Age group
Adult

Sex
Female

Target number of participants
300

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
Scotland

United Kingdom

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)

Sponsor details
Research and Development Office
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Glasgow Royal Infirmary
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Wellbeing (Charity) Ref. CT 2004

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	25/07/2006		Yes	No
Results article	results	01/08/2009		Yes	No