Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Isosorbide Mononitrate (vs. placebo) on induction success in pregnant women

Protocol summary

Summary

The objective of this study is to examine of induction success and maternal & fetal complications of Iso sorbide Mono Nitrate(IMN) on cervical ripening .The inclusion criteria: 1-single pregnancy, 2- cephalic presentation, 3- Bishop Score ≤6, 4-normal AFI>5, 5- regular FHR, 6- intact membrane, 7- gestational age ≥37 weeks. Exclusion criteria are: Uterine contraction (≥3 contraction 45'' in 10 minutes) previous mymomectomy, history of headache, intolerance IMN, cardiopulmonary disease, vaso previa or placenta previa, cord prolepses, classic incision or previous myomectomy, irregular FHR, multiple pregnancy, macrosomia, polyhydramious, severe preeclampsia, maternal short stature. All candidates take an informed consent and assigned randomly into two groups (receiving 40 mg IMN or placebo). Outcomes are : interval between admission to Normal vaginal delivery, type of delivery(NVD-C/S), bleeding level, interval between admission and active phase, neonatal outcomes (APGAR score, NICU admission), maternal outcomes (headache, palpitation), fetal outcome (tacysystole, hyperstimulation syndrome, hypersystole)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803311946N3**
Registration date: **2010-12-08, 1389/09/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-12-08, 1389/09/17

Registrant information

Name

Mandana Mansur Ghanaie

Name of organization / entity

Giulan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Guilan university of medical sciences

Expected recruitment start date

2009-08-27, 1388/06/05

Expected recruitment end date

2011-08-27, 1390/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Isosorbide Mononitrate (vs. placebo) on induction success in pregnant women

Public title

The effect of Isosorbide Mononitrate on induction success

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria: 1-single pregnancy, 2- cephalic presentation, 3- Bishop Score ≤6, 4-normal AFI>5, 5- regular FHR, 6- intact membrane, 7- gestational age ≥37 weeks. Exclusion criteria are: Uterine contraction (≥3 contraction 45'' in 10 minutes) previous mymomectomy,

history of headache, intolerance IMN, cardiopulmonary disease, vaso previa or placenta previa, cord prolepses, classic incision or previous myomectomy, irregular FHR, multiple pregnancy, macrosomia, polyhydramious, severe preeclampsia, maternal short stature.

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice chancellor for research, Guilan University of Medical Sciences

Street address
Opposite of Azodi Studium, Namjo street

City
Rasht

Postal code

Approval date
empty

Ethics committee reference number
3092

Health conditions studied

1

Description of health condition studied
Other assisted single delivery

ICD-10 code
O83

ICD-10 code description
Other assisted single delivery

Primary outcomes

1

Description
labor course

Timepoint
Hospitalization to delivery

Method of measurement
Based on Documented data

2

Description
delivery mode

Timepoint
Post partum

Method of measurement
Based on Documented data

3

Description
bleeding volume in labor and post partum

Timepoint
Control of labor course

Method of measurement
Based on Documented data

4

Description
hospitalization duration and active phase initiation

Timepoint
Control of labor course

Method of measurement
Based on Documented data

Secondary outcomes

1

Description
newborn apgar score

Timepoint
Immediately after delivery

Method of measurement
Based on documented data

2

Description
NICU requirement

Timepoint
Post partum

Method of measurement
Based on documented data

3

Description
the rate of maternal palpitation

Timepoint

During labor

Method of measurement

Based on documented data

4

Description

the occurance of maternal headache

Timepoint

Control during labor & delivery

Method of measurement

Based on documented data

5

Description

the ocurrance of tachysystol/hypersystol and hyperstimulated syndrome

Timepoint

FHR monitoring during labor

Method of measurement

Based on documented data

Intervention groups

1

Description

Isosorbide Mononitrate, 40mg, vaginal for the caces

Category

Treatment - Drugs

2

Description

Placebo for the control group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital, Guilan university of medical sciences

Full name of responsible person

Street address

Alzahra hospital, Namjo street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Guilan University of Medical Sciences

Full name of responsible person

Dr. Abdolrasol Sobhani

Street address

Mellat St., Namjoo Ave.

City

Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research, Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Mandana Mansuor Ghanaie

Position

Assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Reproduction Health Reseach Center, Guilan University of Medical Sciences
Full name of responsible person
Seyede Fatemeh Dalil Hirati
Position
Bs in Midwifery
Other areas of specialty/work
Street address
Reproduction Health research center, Alzahra hospital, Namjo street
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Rasht
Postal code
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty