

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 myomectomy, 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

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Name of organization / entity

Guilan 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 myomectomy,

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 occurrence of maternal headache

Timepoint

Control during labor & delivery

Method of measurement

Based on documented data

5

Description

the occurrence 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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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**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*