

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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  $\leq 6$ , 4-normal AFI $>5$ , 5- regular FHR, 6- intact membrane, 7- gestational age  $\geq 37$  weeks.

Exclusion criteria are: Uterine contraction ( $\geq 3$  contraction 45'' in 10 minutes) previous myomectomy, history of headache, intolerance IMN, cardiopulmonary disease, vasa previa or placenta previa, cord prolapses, 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

Guilan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1322 5624

##### Email address

m\_m\_ghanaie@gums.ac.ir

##### 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  $\leq 6$ , 4-normal AFI $>5$ , 5- regular FHR, 6- intact membrane, 7- gestational age  $\geq 37$  weeks. Exclusion criteria are: Uterine contraction ( $\geq 3$  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**

**Street address**

Reproduction Health research center, Alzahra hospital, Namjo street

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m\_m\_ghanie@gums.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Mandana Mansur Ghanaie

**Position**

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**Web page address****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**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*