# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## The Effect of Vaginal Administration of Isosorbide Mononitrate on Cervical Ripening and Iduction Of Labor In Postterm Pregnancy

## Protocol summary


**Summary**

This clinical trial is double blind, randomized with Placebo-controlled groups that will be carried out in Sina hospital in Ahvaz. Participants will be women with postdate pregnancy who require labor induction. Eligible women are interviewed following a visit by gynecologist and study goals are explained completely for them. Written agreement will be obtained and their demographic characteristics will be recorded by the researcher. After physical examination, cervix bishop score is determined and then 40 mg Isosorbite mononitrate or placebo prepared by pharmacist will be administered into the posterior vaginal fornix. Mothers will be under supervision for 2 hours before they are allowed to go home.The time of next visit is set and they are advised to avoid taking any drug or intercourse. They will be asked to return immediately to hospital if there are some painful contractions, premature rupture of membrane, vaginal bleeding or bloody show. Nevertheless all subjects should return after 12 hours and will all of them will be admitted. The second dose of drug or placebo is administrated and after 24 hours from the first visit, the bishop score of cervix is determined and classic induction with oxytocin will begin if they are not in active labor. Bishop score changes, duration of delivery induction, time from start of oxytocin to active phase, duration of active phase, second and third stage of labor, the amount of consumed oxytocin, mode of delivery, any kind of maternal and fetal outcome will be registered.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201011305234N1**
Registration date: **2010-12-29, 1389/10/08**
Registration timing: **na**
Last update:
Update count: **0**

**Registration date**

2010-12-29, 1389/10/08

**Registrant information**


**Name**

Hamideh Yazdizadeh

**Name of organization / entity**

Faculty of nursery and midwifery-Ahvaz jondishapur unversity of medical science

**Country**

Iran (Islamic Republic of)

**Phone**

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**Email address**

yazdizadeh_h@ajums.ac.ir


**Recruitment status**

**Not enough for processing**

**Funding source**

Research Deputy, Ahvaz Jondishapur university of medical science

**Expected recruitment start date**

2010-12-06, 1389/09/15

**Expected recruitment end date**

2010-08-22, 1389/05/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect of Vaginal Administration of Isosorbide Mononitrate on Cervical Ripening and Iduction Of Labor In Postterm Pregnancy

**Public title**

Cervical ripening before induction of labor

**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: age between 18-35, nullipara, Bishop sore equal or low of 5, To have Reliable LMP or sonography in first trimester, To have BMI 19.6-26 in first trimester, Cephalic presentation, Fetal Weigth=2500-4000, single fetus, To have NST and biophysical profil in last 48 hours, Gestational age: 40-42 w Exclusion criteria: Congenital abnormalitywith sono in the second trimester, preclampsia, Headache, post C/S, Active genital herpes, Addict to alcohol, polyhydroamnios, placenta previa or doubt to placenta abruption, previous breath or heard disease, to have any conterindication for induction of labor, BPs<90
**Age**
From **18 years** old to **35 years** old
**Gender**
Female

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **80**
**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**
Ahvaz Jondishapur university of medial science
**Street address**
Golestan Hiway
**City**
Ahvaz
**Postal code**
**Approval date**
2010-11-28, 1389/09/07
**Ethics committee reference number**
ETH-O16

## Health conditions studied

**1**

**Description of health condition studied**
Cervical ripening and induction of labor
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Cervical ripening
**Timepoint**
24 hours
**Method of measurement**
measurement of cervix bishop score

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
vaginal administration oral tablet isosorbite mononitrate 20 mg, two tablets per 12 hours before start of induction of labor with oxytocin in interventional group
**Category**
Treatment - Drugs

**2**

**Description**
In plasebo group: to give plasebo tablet made of caco3, Odisel, Mg estearate 1% that will be made by Ahvaz Faculty of pharmacy, 24 hours before start of induction of labor with oxytocin
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
sina hospital
**Full name of responsible person**
**Street address**
**City**
AHVAZ

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Research Deputy, Ahvaz Jondishapur university of

medical science

**Full name of responsible person**
Dr.Mostafa Feghhi

**Street address**
Research Deputy,Ahvaz Jondishapur university of Medical Science

**City**
Ahvaz

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Research Deputy, Ahvaz Jondishapur university of medical science

**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**
Ahvaz Jondishapur university of medical science - Faculty of nursing and midwifery

**Full name of responsible person**
Hamideh Yazdizadeh

**Position**
Mastering of Science student in Midwifery

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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**Position**
PhD in Society Nutrition

**Other areas of specialty/work**

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## Person responsible for updating data

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Golestan Highwey

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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*