

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The Effect of Vaginal Administration of Isosorbide Mononitrate on Cervical Ripening and Induction 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 Isosorbide 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 university of medical science

Country

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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 Induction 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 score 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 Weight=2500-4000, single fetus, To have NST and biophysical profile in last 48 hours, Gestational age: 40-42 w
Exclusion criteria: Congenital abnormality with sono in the second trimester, preeclampsia, Headache, post C/S, Active genital herpes, Addict to alcohol, polyhydramnios, placenta previa or doubt to placenta abruption, previous breath or heard disease, to have any contraindication 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 medical 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 placebo group: to give placebo tablet made of caco3, Odisel, Mg stearate 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 Fegghi

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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Position

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Other areas of specialty/work

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Web page address

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