

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of vaginal Isosorbaid mononitrat and vaginal estradiol and placebo effect on cervix ripening in post term pregnancy

#### Protocol summary

##### Summary

Purpose: Comparison of vaginal Isosorbaid mononitrat and vaginal estradiol and placebo effect on cervix ripening in post term pregnancy Design study: a randomized, triple blind, placebo-controlled The methods used included: (A): Key inclusion criteria: singleton pregnancy; cephalic presentation; intact membranes; BS less than 6; the result of normal fetal health monitoring; lack of uterine contractions; the absence of systemic problems; age 15 - 35 Main exclusion criteria: women with preeclampsia; history of previous cesarean; active genital herpes; poly Hydramnious; placenta previa or placental abruption risk; membrane rupture; history of Cardiac or respiratory disease; the presence of any contra indication for labor induction; systolic blood pressure less than 90 mmHg Sample size: 99 (B) Interventions in the study: From all of mothers, we will obtain a NST, and then patients will be divided into three groups according to randomized block plan. At the first group, vaginal estradiol 25 micro gram, at the second group, vaginal isosorbide mononitrate 20 mg, and at the third group, placebo placed in the posterior fornix and 12 hours after hospitalized, If BS is less than 6, previous dose is repeated again. Cervical examination is done every 2 hours. (C) The intervention time: At arrival, and 12 hours later. (D) The primary outcome or consequences of the study: to improve the cervical Bishop score, better response to induction of labor, cesarean section rate reduction

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015053122507N1**

Registration date: **2015-08-21, 1394/05/30**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-08-21, 1394/05/30

##### Registrant information

###### Name

Nushin Chamheidar

###### Name of organization / entity

Ardabil University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3352 2100

###### Email address

n.chamheidar@arums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Ardabil University of Medical Sciences

##### Expected recruitment start date

2015-06-06, 1394/03/16

##### Expected recruitment end date

2016-02-05, 1394/11/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of vaginal Isosorbaid mononitrat and vaginal estradiol and placebo effect on cervix ripening in post term pregnancy

##### Public title

preparation for delivery in late pregnancy

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: singleton pregnancy; cephalic presentation; intact membranes; BS less than 6; the result of normal fetal health monitoring; lack of uterine contractions; the absence of systemic problems in the history; clinical examination; age 15 to 35 Exclusion criteria: women with preeclampsia; history of previous cesarean; active genital herpes; poly Hydramniou; placenta previa or placental abruption risk; membrane rupture; history of Cardiac or respiratory disease; the presence of any contra indication for labor induction; systolic blood pressure less than 90 mmHg

## Age

From **15 years** old to **35 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **99**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ardabil University of Medical Sciences

##### Street address

Ardabil university of medical sciences, Pardis Office Complex, end of University Avenue, Janbazan Square, Ardabil

##### City

ardabil

##### Postal code

5618985991

#### Approval date

2015-02-16, 1393/11/27

#### Ethics committee reference number

Arums.Rec.93.63

## Health conditions studied

### 1

#### Description of health condition studied

vaginal Isosorbaid mononitrat and vaginal estradiol and Placebo effect on cervix ripening

#### ICD-10 code

P08

#### ICD-10 code description

Disorders related to long gestation and high birth weight

## Primary outcomes

### 1

#### Description

bishop score (cervix ripening)

#### Timepoint

at the visit, 12 hours and 24 hours later.

#### Method of measurement

Vaginal examination (According to Williams reference table to determine the Bishop score)

## Secondary outcomes

### 1

#### Description

From active phase to full dilatation

#### Timepoint

During the study

#### Method of measurement

Observation and examination

### 2

#### Description

From full dilatation to delivery

#### Timepoint

During the study

#### Method of measurement

Observation and examination

### 3

#### Description

From Induction to active phase

#### Timepoint

During the study

#### Method of measurement

Observation and examination

### 4

#### Description

Delivery

#### Timepoint

During the study

#### Method of measurement

Observation and examination

### 5

#### Description

Maternal side effects (headache, nausea, vomiting, and dizziness)

**Timepoint**

During the study

**Method of measurement**

Observation and examination

**6**

**Description**

The consequences of neonatal (first and fifth minute Apgar score, gender and birth weight, infant hospitalized in the Intensive Care Unit, Meconium defecation)

**Timepoint**

During the study

**Method of measurement**

Observation and examination

**Intervention groups**

**1**

**Description**

From all of mothers, we will obtain a NST, After ensuring fetal heart rate pattern, patients randomized block design are divided into three groups. At the vaginal isosorbide mononitrate group, 1 tablet 20 mg isosorbide mononitrate placed in the posterior fornix (outpatients) and 12 hours after hospitalized, BS again determined. If less than 6 previous dose is repeated again. Cervical examinations conducted by the investigator every 2 hours.

**Category**

Treatment - Drugs

**2**

**Description**

From all of mothers, we will obtain a NST, After ensuring fetal heart rate pattern, patients randomized block design are divided into three groups. At the vaginal estradiol group, 1 tablet 25 micro gram placed in the posterior fornix (outpatients) and 12 hours after hospitalized, BS again determined. If less than 6 previous dose is repeated again. Cervical examinations conducted by the investigator every 2 hours.

**Category**

Treatment - Drugs

**3**

**Description**

From all of mothers, we will obtain a NST, After ensuring fetal heart rate pattern, patients randomized block design are divided into three groups. At the Placebo group, 1 Placebo tablet placed in the posterior fornix (outpatients) and 12 hours after hospitalized, BS again determined. If less than 6 previous dose is repeated again. Cervical examinations conducted by the investigator every 2 hours.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Alavi Hospital

**Full name of responsible person**

Nushin Chamheidar

**Street address**

Alavi Hospital, sport squire, Ardabil

**City**

Aedabil

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Deputy Director of Research and Technology of Ardabil University of Medical Sciences

**Full name of responsible person**

Dr Shahram Habibzadeh

**Street address**

Ardabil university of medical sciences, Pardis Office Complex, end of University Avenue, Janbazan Square, Ardabil

**City**

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Deputy Director of Research and Technology of Ardabil 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**

Ardabil University of Medical Sciences

**Full name of responsible person**

Nushin Chamheidar

**Position**

obstetric and gynecology resident

**Other areas of specialty/work**

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Assistant Professor

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**Position**

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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*