Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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 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

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 squre, 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

Ardabil

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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Person responsible for scientific inquiries

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nushin.chamheidar@gmail.com
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