Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

A comparison of vaginal and oral dose of misoprostol for labor induction in post-term pregnancies

Protocol summary

Summary

This study compares oral misoprostol with vaginal misoprostol for induction of labor in post-term pregnancies. A total of 180 post-term pregnant women who admitted to the labor ward of Sanandaj Besat Hospital selected and randomly divided into three groups (each group consisting of 60 people). The induction was performed for the first group with 100 mcg misoprostol orally, for the second group with 50 mcg misoprostol orally and for the third group with 25 mcg misoprostol vaginally. Drugs were in three uniform boxes and after grouping the patients were given to them. The researcher was unaware of any grouping. After administration the desired group was recorded. Inclusion criteria included Gestational age (GA) greater or equal to 40 weeks and 6 days with cephalic presentation and Bishop score greater than 4 and height of 150 cm. Exclusion criteria included contraindications to receive misoprostol (allergies, asthma, Pelvic Inflammatory Disease, Acute Cerebrovascular Disease, Coronary Artery Disease, seizures) and also placenta previa , history of previous cesarean section or uterine surgery, Cephalopelvic Disproportion , Bishop score greater than 4, and abnormal vaginal bleeding. Data were analyzed by SPSS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061412789N3**
Registration date: **2014-09-15, 1393/06/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-09-15, 1393/06/24

Registrant information

Name
Masoud Rasolabady
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kurdistan University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of vaginal and oral dose of misoprostol for labor induction in post-term pregnancies

Public title

Effect of misoprostol in labor induction in post-term pregnancies

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age (GA) greater or equal to 40 weeks and 6 days with cephalic presentation and Bishop score greater than 4 and a height of 150 cm. Exclusion criteria included contraindications to receive

misoprostol (allergies, asthma, Pelvic Inflammatory Disease, Acute Cerebrovascular Disease, Coronary Artery Disease, seizures) and also placenta previa , history of previous cesarean section or uterine surgery, Cephalopelvic Disproportion , Bishop score greater than 4, and abnormal vaginal bleeding.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Subjects were selected and randomly divided into three groups through block randomization method. Drugs are placed in three same packages that labeled as (1, 2, and 3) and give to the nurse who is responsible for delivery. There is a questionnaire with each patient which determined patients grouping. Drugs would be administered to patients according to their grouping by nurse, and then the required information recorded. Researcher and monitoring committee are unaware of patients grouping.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Pasdaran St., Kurdistan University of Medical Sciences

City

Sanandaj

Postal code

Approval date

2013-09-18, 1392/06/27

Ethics committee reference number

14/21648

Health conditions studied

1

Description of health condition studied

Efficacy on induction of labor

ICD-10 code

O61.0

ICD-10 code description

Failed medical induction of labour

Primary outcomes

1

Description

Interval from induction to delivery

Timepoint

From induction to delivery every 1 hour

Method of measurement

Vaginal exam for evaluation of dilatation and effacement

Secondary outcomes

1

Description

Fetal distress

Timepoint

At delivery time and 48 hours after that

Method of measurement

Based on the examination of the fetal heart rate and is determined by a specialist

Intervention groups

1

Description

Labor induction performs in group 3 by 25 micro grams misoprostol vaginally (posterior fornix). Based on conditions every 6 hours for 4 doses repeated. Before repeating each dose, vaginal examination to determine Bishop score will be done.

Category

Treatment - Drugs

2

Description

Labor induction performs in group 1 by 100 micro grams misoprostol orally. Based on conditions every 6 hours for 4 doses repeated. Before repeating each dose, vaginal examination to determine Bishop score will be done.

Category

Treatment - Drugs

3

Description

Labor induction performs in group 2 by 50 micro grams misoprostol orally. Based on conditions every 6 hours for

4 doses repeated. Before repeating each dose, vaginal examination to determine Bishop score will be done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sanandaj Besat Hospital

Full name of responsible person

Soosan Mirza Mohammadi Sadegh

Street address

Keshavarz St., Besat Hospital

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Kurdistan University of Medical Sciences

Full name of responsible person

Fardin Gharibi

Street address

Pasdaran St., Kurdistan University of Medical Sciences

City

Sanandaj

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, Kurdistan 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

Kurdistan University of Medical Sciences

Full name of responsible person

Soosan Mirza Mohammadi Sadegh

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

Soosan Mirza Mohammadi Sadegh

Position

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Other areas of specialty/work

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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