

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

A comparison between induction of labor with 3 methods of titrated oral misoprostol, constant dose of oral misoprostol and folly catheter with extra amniotic saline infusion (EASI), in women with unfavorable cervix.

Protocol summary

Summary

Objective: Comparison between induction of labor with 3 methods of titrated oral misoprostol, constant dose of oral misoprostol and folly catheter with extra amniotic saline infusion (EASI), in women with unfavorable cervix. Design: Clinical trial. Setting and conduct: non randomized, not blind. Participants: Pregnant women with inclusion criteria: maternal age between 18-40 years old; gestational age of more than 37 weeks; singleton; cephalic presentation; intact membrane and Bishop Score of less than 6. Exclusion criteria were any sign of fetal distress, placenta previa and any vaginal bleeding of more than bloody show, history of any surgery on uterus including cesarean section, and known uterine anomaly, intra uterine fetal death, and known hypersensitivity to misoprostol. Intervention: induction of labor with titrated oral misoprostol, constant dose of oral misoprostol and folly catheter with extra amniotic saline infusion (EASI) Main outcome: The main outcome was the number of vaginal deliveries during the first 24 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702282624N22**

Registration date: **2017-04-03, 1396/01/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-03, 1396/01/14

Registrant information

Name

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator.

Expected recruitment start date

2014-04-05, 1393/01/16

Expected recruitment end date

2015-05-06, 1394/02/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between induction of labor with 3 methods of titrated oral misoprostol, constant dose of oral misoprostol and folly catheter with extra amniotic saline infusion (EASI), in women with unfavorable cervix.

Public title

Induction of labor with 3 different methods.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : maternal age between 18-40 years old; gestational age of more than 37 weeks ; singleton, cephalic presentation, intact membrane and Bishop Score of less than 6. Exclusion criteria : any sign of fetal

distress; placenta previa and any vaginal bleeding of more than bloody show; history of any surgery on uterus including cesarean section; known uterine anomaly; intra uterine fetal death, and known hypersensitivity to misoprostol.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran.University of Medical Sciences

Street address

Hemmat highway, Chamran Cross

City

Tehran

Postal code

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

92/1345/

Health conditions studied

1

Description of health condition studied

Delivery

ICD-10 code

O00-O99

ICD-10 code description

Pregnancy, childbirth and the puerperium

2

Description of health condition studied

Outcome of delivery

ICD-10 code

Z37

ICD-10 code description

Outcome of delivery

Primary outcomes

1

Description

Delivery during the first 24 hours after intervention.

Timepoint

24 hours

Method of measurement

Data sheets

Secondary outcomes

1

Description

duration of the stages of labor

Timepoint

1 hour

Method of measurement

Data sheets

2

Description

The adverse effects in mothers.

Timepoint

each hour

Method of measurement

Data sheets

3

Description

The adverse effects in neonates.

Timepoint

After birth up to discharge.

Method of measurement

Data sheets

Intervention groups

1

Description

In oral titrated misoprostol group: 200µg misoprostol tablet will be solved in 200 milliliter of water (this solution is stable in the room temperature and contains 1µg misoprostol in 1mlit of solution). First, 20 milt (20µg) of misoprostol will be administered hourly for 4 hours. Then in spite of not having good contractions, 40 milt (40µg) of misoprostol solution will be administered every 1 hour for 4 doses and will be repeated after 4 hours with

60mlit (60µg) of misoprostol solution for a maximum of 4 doses (in total 480µg).

Category

Treatment - Drugs

2

Description

In oral misoprostol group, 50µg misoprostol will be administered and women will be followed up to 4 hours. FHR and uterine contractions will be checked hourly. In the cases of not having suitable contractions after 4 hours, another 50 µg of misoprostol will be administered every 4 hours until obtaining good contractions or up to maximum 6 doses (300 µg totals). Then the women will be followed up to delivery.

Category

Treatment - Drugs

3

Description

In the EASI group, folly catheter of number 18 was introduced through cervical canal and was filled with 30mlit distilled water and was fixed above the internal cervical OS, and was connected to normal saline solution. The normal saline was entered the uterus with the rate of 30 drops per minute. After expulsion of folly catheter, oxytocin was started in the amount of 25 milliunits per minute and was increased every 15 minutes up to 40 milliunits per minute.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Teaching Hospital

Full name of responsible person

Maryam Kashanian

Street address

Molavi avenue, Molavi Cross Road.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research ,Iran University of Medical Sciences.

Full name of responsible person

Dr Seyed Ali Javad Mousavi

Street address

Hemmat High way, Junction of Chamran Highway.

City

Tehran

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 ,Iran 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

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

Professor.

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