Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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/د

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 titrared 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