Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the efficacy and complications of sublingual versus vaginal misoprostol for induction of laborfor women in term pregnancy

Protocol summary

Summary

Goal of the study is to compae the efficacy and complications of sublingual versus vaginal misoprostol for induction of labor by a triple- blind study for women in term pregnancy.Goal of the study: Comparison of the efficacy and complications of sublingual versus vaginal misoprostol for induction of labor by a triple- blind study for women in term pregnancy. 200 pregnent women with the inclusion criteria will enter the study. Sublingual and vaginal tablets containing 25 µg misoprostol and placebo will be prepared for the study by pharmaceutics division of Shiraz University of Medical Sciences. Medication-packages will be prepared and coded. All of the packages will contain two plastic bags, one of them sublingual tablets and the other bag vaginal suppositories. In each package only one of the plastic bags will contain misoprostol and the other one is placebo. Both types of preparations will be used for every woman who enters the study. Only the pharmaceutics will know that which bag contained the active form of medication. Medications will be repeated every 4 hours until cervical Bishop Score advances to more than 8. Close observation of the mother and continuous fetal heart monitoring will be performed for all of these patients. After the final analysis the code will be broken.

General information

Acronym

Misoprostol

IRCT registration information

IRCT registration number: **IRCT201402096541N3**
Registration date: **2014-02-17, 1392/11/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-02-17, 1392/11/28

Registrant information

Name
Bahia Namavar Jahromi
Name of organization / entity
Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences- Vice Chancellor for research

Expected recruitment start date

2009-02-01, 1387/11/13

Expected recruitment end date

2013-02-28, 1391/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and complications of sublingual versus vaginal misoprostol for induction of laborfor women in term pregnancy

Public title

Comparison of the efficacy and complications of sublingual versus vaginal misoprostol for induction of laborfor women in term pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria:first singleton alive pregnancy; gestational age of ≥37 weeks: cephalic presentation: estimated fetal weight of less than 4000 grams; Bishop Score <7. Exclusion criteria: : hypersensitivity to prostaglandins; previous uterine scar; fetal congenital malformations; intrauterine growth restriction; non-reassuring fetal heart; gestational age <37 weeks; oligohydramnious.
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **200**
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
Ethics Review Board, Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand Street, Shiraz.
City
Shiraz
Postal code
Approval date
2011-06-02, 1390/03/12
Ethics committee reference number
CT-90-5589

Health conditions studied

1

Description of health condition studied
Pregnancy , childbirth and the puerperium (O00-O99)
ICD-10 code
O61
ICD-10 code description
failed induction of labour

Primary outcomes

1

Description
the time needed for delivery
Timepoint
Medication starting time to delivery
Method of measurement
Measurement of the time needed after aplication of medication to delivery

2

Description
Fetal safety
Timepoint
at delivery
Method of measurement
By evaluation of neonata blood gas at birth

Secondary outcomes

1

Description
the effect of drugs on the fetal safety
Timepoint
After birth
Method of measurement
Apgar scors and NICU admissions

2

Description
Fetal safety
Timepoint
during labor
Method of measurement
meconium passage

Intervention groups

1

Description
The control group: will recieve vaginal supositories containing 25 microgram misoprostol and sublingual tablets of placebo.
Category
Treatment - Drugs

2

Description
The intervention group: will recieve 25 microgram tablets of misoprostol and vaginal supositories containing placebo.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez Hospital and Hazrate Zeinab Hospitals
Full name of responsible person
Bahia namavar Jahromi
Street address
dep. of OB-GYN, Shahid Faghihi Hospital, Shiraz, Iran.
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences- Vice Chancellor for Research
Full name of responsible person
Dr. Gholamreza Hatam
Street address
Shahid Faghihi Hospital, Shiraz , Iran
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences- Vice Chancellor for Research
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
School of Medicine, Shiraz University of Medical Sciences
Full name of responsible person
Dr. Bahia Namavar Jahromi
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Person responsible for scientific inquiries

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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