

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

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

Protocol summary

2014-02-17, 1392/11/28

Summary

Goal of the study is to compare 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 pregnant 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 pharmaceuticals 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 pharmaceuticals 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

Registrant information

Name

Bahia Namavar Jahromi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 2365

Email address

namavarb@sums.ac.ir

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 labor for women in term pregnancy

Public title

Comparison of the efficacy and complications of sublingual versus vaginal misoprostol for induction of labor for 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; oligohydramnios.

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 application of medication to delivery

2

Description

Fetal safety

Timepoint

at delivery

Method of measurement

By evaluation of neonatal blood gas at birth

Secondary outcomes

1

Description

the effect of drugs on the fetal safety

Timepoint

After birth

Method of measurement

Apgar scores and NICU admissions

2

Description

Fetal safety

Timepoint

during labor

Method of measurement

meconium passage

Intervention groups

1

Description

The control group: will receive vaginal suppositories containing 25 microgram misoprostol and sublingual tablets of placebo.

Category

Treatment - Drugs

2

Description

The intervention group: will receive 25 microgram tablets of misoprostol and vaginal suppositories 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

Position

Professor in the department of OB-GYN

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences- Vice Chancellor for research

Full name of responsible person

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Position

professor

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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