

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of characteristics of women undergoing labor induction with oxytocin and oral misoprostol

Protocol summary

Summary

The purpose of this study was to compare labor induction with oral misoprostol and labor induction with oxytocin. A total of 65 women with an induction were randomized into 2 groups. Inclusion criteria were: Gestational age 39 to 42 weeks; weighing an estimated birth to 4000 g; the heartbeat of the fetus; Cephalic presentation. The misoprostol group received 25 mcg every two hours for up to 24 hours for induction. The oxytocin group received an infusion of 10 IU. The time from induction to delivery and induction to the beginning of the active phase and successful inductions within 12, 18, and 24 hours were recorded in addition to caesarean sections and reasons.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012080610511N1**
Registration date: **2012-09-13, 1391/06/23**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-09-13, 1391/06/23

Registrant information

Name

Maryam Karamali

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1278 0660

Email address

dr.karamali@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2010-02-20, 1388/12/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of characteristics of women undergoing labor induction with oxytocin and oral misoprostol

Public title

Comparison of characteristics of women undergoing labor induction with oxytocin and oral misoprostol

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 39 to 42 weeks of gestational age; Estimated fetal weight 4000 g; Normal fetal heart rate; cephalic presentation; Absence of uterine contractions; Singleton pregnancy; Bishop score of 7 or less. Exclusion criteria: Previous uterine surgery including caesarean section; Intrauterine fetal death IUGR; Oligohydroamnion; Placenta previa; Umbilical cord Prolapse; Corioamnionitis symptoms; Symptoms of active herpes; kidney or liver disease; NST Non-Stress Test reactive bread; Contraindication for Administration of prostaglandin. Contraindication for induction of labor; Vaginal bleeding of unknown cause.

Age

From **17 years** old to **36 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 65

Randomization (investigator's opinion)

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

Shahid Beheshti University Of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences,
Velenjak St, Shahid chamran Highway

City

Tehran

Postal code

1985717443

Approval date

2010-02-17, 1388/11/28

Ethics committee reference number

111

Health conditions studied

1

Description of health condition studied

Induction of Labor

ICD-10 code

O61.0

ICD-10 code description

Failed medical induction of labour

Primary outcomes

1

Description

Time of induction to active phase

Timepoint

During 12, 18, 24 hours

Method of measurement

clock

2

Description

Start time of induction to delivery

Timepoint

During 12, 18, 24 hours

Method of measurement

clock

Secondary outcomes

empty

Intervention groups

1

Description

First group received oral misoprostol, 25 mcg every 2 hours for up to 24 hours

Category

Treatment - Drugs

2

Description

The oxytocin group received an infusion of 10 IU. Starting with four drops per minute, which was doubled each quarter hour up to 64 drops.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadae Tajrish Hospital

Full name of responsible person

Dr Maryam Karamali

Street address

Hospital Shohada, Tajrish St. District 01

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Rahmati Roodsari

Street address

Shahid Beheshti University of Medical Sciences, Velenjak Street, Shahid Chamran High Way

City

Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of medical sciences
Full name of responsible person
Dr Maryam Karamali
Position
Specialist in Obstetrics & Gynecology
Other areas of specialty/work
Street address
Shohadaetajrish Hospital
City
Tehran
Postal code
1985717443
Phone
+98 21 2271 9013
Fax
Email
dr.karamali@arakmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of medical sciences
Full name of responsible person
Dr Maryam Karamali
Position
Specialist in Obstetrics & Gynecology
Other areas of specialty/work
Street address

Shahid Beheshti University of Medical Sciences.Velenjak street, Shahid Chamran High way
City
Tehran
Postal code
1985717443
Phone
00892122719013
Fax
+98 21 2271 1200
Email
Dr.karamali@arakmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of medical sciences
Full name of responsible person
Dr Maryam Karamali
Position
Specialist in Obstetrics & Gynecology
Other areas of specialty/work
Street address
Shahid Beheshti University of medical sciences,
Velenjak, Shahid Chamran Highway
City
Tehran
Postal code
1985717443
Phone
+98 21 2271 9013
Fax
+98 21 2271 1200
Email
dr.karamali@arakmu.ac.ir
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