Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Nov 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 oxcytocin. 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; Oligohidroamnius; 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 recevied 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 sceinces

Full name of responsible person

Dr Maryam Karamali

Position

Specialist in Obestetrics & Gynocology

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

Spesialist in Obestetrics & Gynocology

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 Obestetrics & Gynocology

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