Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jul 2026

Induction and augmentation of labor with oral misoprostol versus oxytocin in term pregnancy: randomized controlled trial

Protocol summary

Summary

The aim of the present study was to evaluate the effectiveness and the safety of orally administered misoprostol in comparison to intravenously infused oxytocin for labor induction in term pregnant women. Between 2008 and 2010, a total of 285 term pregnant women whom were candidate for vaginal delivery assessed for eligibility to enter the study and were randomly assigned to one of two groups according to the method of treatment, misoprostol or oxytocin. The misoprostol group received 25 µg every two hours for up to 24 hours for induction. The oxytocin group received an infusion of 10 IU which was gradually increased. 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.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012061910068N1**
Registration date: **2012-07-05, 1391/04/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-07-05, 1391/04/15

Registrant information

Name

Aida Moeini

Name of organization / entity

Department of Obstetrics and Gynecology, Shahid Beheshti University of Medical Science, Tehran, Iran

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8000

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Recruitment status

Recruitment complete

Funding source

Shaheed Beheshti University of Medical Sciences

Expected recruitment start date

2008-01-01, 1386/10/11

Expected recruitment end date

2010-01-01, 1388/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Induction and augmentation of labor with oral misoprostol versus oxytocin in term pregnancy: randomized controlled trial

Public title

Labor induction in term pregnant women of with oral misoprostol or oxytocin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: term pregnant women whom were candidate for vaginal delivery; gestational age of 38 to 42 weeks; birth weight of maximally 4000 grams; normal fetal heart rate; cephalic presentation; lack of uterine contractures; single pregnancy and Bishop Score of six and less. The exclusion criteria were lack of satisfaction for incorporation in the study; having a positive history of uterine surgery including cesarean; intrauterine growth retardation (IUGR); oligohydramnios; placenta previa; umbilical cord prolapse; active herpes infection;

symptoms of chorioamnionitis; hepatic or renal disease; non-reactive contraindications for prostaglandins use; contraindications for labor induction and idiopathic vaginal bleeding.

Age
From **14 years** old to **40 years** old

Gender
Female

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **285**

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
Shaheed Beheshti University of Medical Sciences Ethics Committee

Street address
Department of Obstetrics and Gynecology, Tajrish Hospital, Tajrish Sq, Tehran, Iran.

City
Tehran

Postal code

Approval date
2007-10-01, 1386/07/09

Ethics committee reference number
69

Health conditions studied

1

Description of health condition studied
labor induction

ICD-10 code
O00-O08

ICD-10 code description
Pregnancy with abortive outcome

Primary outcomes

1

Description
The time from induction to delivery

Timepoint
12, 18, and 24 hours during labor

Method of measurement
Data recording

2

Description
The time from induction to the beginning of the active phase

Timepoint
12, 18, and 24 hours during labor

Method of measurement
Data recording

3

Description
Mode of delivery

Timepoint
12, 18, and 24 hours during labor

Method of measurement
Data recording

Secondary outcomes

1

Description
Maternal complications

Timepoint
Peri labor phase

Method of measurement
Data record

2

Description
Fetal and neonatal status

Timepoint
Peri labor phase

Method of measurement
Data record

Intervention groups

1

Description
In the oxytocin group, infusion rate of 2 mIU/min was prescribed for induction and gradually increased by 2 mIU/min every 15 minutes to a maximum dose of 36 mIU/min. In presence of any tachysystole (5 contractions in a 10-minute interval) or hypertonus (single contractions lasting 2 minutes or longer), or changes in fetal heart rate associated with tachysystole or

hypertonus, infusion rate was decreased or stopped.

Category

Treatment - Drugs

2

Description

Initiation of labor induction was the time at which the first misoprostol dose was administered (group 1) or the oxytocin infusion was started (group 2). In the misoprostol group, a tablet of 200 µg was dissolved in 200cc of water and 25cc was administered every two hours for up to 24 hours (10). The maximum dose was 300 µg. If the ideal pattern of contractions (at least 3 contractions per 10 minutes) was reached, misoprostol was no longer administered. Fetal heart monitoring and uterine contraction were also recorded.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

Seyed Jalaledin Khoshnevis

Street address

Shohada Hospital - Tajrish square

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 Science

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

Department of Obstetrics and Gynecology, Shahid Beheshti University of Medical Science

Full name of responsible person

Aida Moeini

Position

M.D.

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Obstetrics and Gynecology, Shahid Beheshti University of Medical Science

Full name of responsible person

Rezvan Aalami-Harandi

Position

Assistant Professor

Other areas of specialty/work

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Position

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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