

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

comparison the effect of oral Misoprostol versus Oxytocin on labor augmentation in pregnant women

Protocol summary

Summary

Prolonged labor is a common problem, especially among nulliparous women. It can result in a negative birth experience. The aim of the present study is to evaluate the effectiveness and the safety of orally administered misoprostol for labor augmentation among women at 36 to 42 weeks of gestation with spontaneous onset of active labor and compare it with intravenously infused oxytocin. A total of 250 term pregnant women with spontaneous onset of active labor whom are candidate for vaginal delivery assess for eligibility to enter the study. Women meeting the general selection criteria with regular contractions and an effaced cervix dilated between 3 and 9 cm, and who have inadequate uterine contractions (two or fewer contractions every 10 minutes) during the first stage of labor, were randomly assigned to titrated oral misoprostol or intravenous oxytocin. The misoprostol group received 25 µg every two hours (maximum doses of 300µg). The oxytocin group received an infusion of 10 IU which was gradually increased. Our study was designed to carry out between 2009 and 2011. The primary parameters used to evaluate efficacy were the interval from the start of augmentation to vaginal delivery and the percentage of women who delivered their newborns vaginally within 12 or 24 hours of this interval. Maternal and neonatal complications were also assessed between 2 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102910068N2**

Registration date: **2012-11-28, 1391/09/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-28, 1391/09/08

Registrant information

Name

Aida Moeini

Name of organization / entity

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

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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

2009-01-01, 1387/10/12

Expected recruitment end date

2011-01-01, 1389/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison the effect of oral Misoprostol versus Oxytocin on labor augmentation in pregnant women

Public title

comparison of Misoprostol with Oxytocin on labor augmentation in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pregnancy between 36 and 42 weeks of gestation; a live singleton fetus in cephalic presentation; no history of uterine surgery; spontaneous onset of active labor with regular contractions; an effaced cervix dilated between 3 cm and 9 cm; a reassuring fetal heart rate (FHR) pattern. Exclusion criteria: nonreassuring FHR pattern; parity greater than five; any contraindication to labor or vaginal delivery or both; epidural analgesia; significant maternal cardiac; renal or hepatic disease; hypersensitivity to misoprostol or prostaglandin analogues.

Age

From **16 years** old to **45 years** old

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **250**

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 science

Street address

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

City

Tehran

Postal code

Approval date

2008-08-01, 1387/05/11

Ethics committee reference number

310

Health conditions studied

1

Description of health condition studied

Long labour

ICD-10 code

O63.1

ICD-10 code description

Prolonged second stage (of labour)

Primary outcomes

1

Description

the time from augmentation to vaginal delivery

Timepoint

12 and 24 hours during labor

Method of measurement

data recording

2

Description

mode of delivery

Timepoint

12 and 24 hours during labor

Method of measurement

data recording

Secondary outcomes

1

Description

Fetal and neonatal status

Timepoint

peri labor phase

Method of measurement

data record

2

Description

maternal complications

Timepoint

peri labor phase

Method of measurement

data record

Intervention groups

1

Description

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. The maximum dose was 300 µg. Fetal heart monitoring and uterine contraction were also recorded. Adequate uterine contractions were defined as three or more in 10 minutes over 30-minute windows. Once uterine activity was adequate over 1 hour, no further misoprostol was given.

Category

Treatment - Drugs

2

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

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Rezvan Aalami-Harandi

Street address

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

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

Seyed Jaleddin Khoshnevis

Street address

Shohada Hospital - Tajrish square

City

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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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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