Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
Country
Iran (Islamic Republic of)
Phone
+98 21 2271 8000
Email address
a.moeini64@gmail.com

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 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

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

City
Tehran

Postal code

Phone
+98 21 2271 8000

Fax

Email
a.moeini64@gmail.com

Web page address

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

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

City
Tehran

Postal code

Phone
+98 21 2271 8000

Fax

Email
mahmaz2002@yahoo.com

Web page address

Person responsible for updating data

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

Street address
Department of Obstetrics and Gynecology, Tajrish

Hospital, Tajrish Sq, Tehran, Iran.

City

Tehran

Postal code

Phone

+98 21 2271 8000

Fax

Email

a.moeini64@gmail.com

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