Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison of vaginal misoprostol tablet and oxytocin in induction of labor at term pregnancy

Protocol summary

Summary

Abstract: Objectives: Recently elective inductions of labor at term have increased dramatically which may be in part due to patient and clinicians desire to arrange a convenient time of delivery. Termination of pregnancy before emerging labor pain is an important concern. Because induction of labor is one of the most commonly performed obstetrical procedures clinicians all over the world investigate to find a safe technique for mother and neonate. Labor induction with PGE1 is one of the selections. Our objective was to compare vaginal delivery, maternal, fetal and neonatal complication between induction of labor with oxytocin and misoprostol. Methods: we selected one hundred - two cases with term pregnancy , not in active labor, singleton pregnancy, vertex presentation, normal fetal heart rate reactivity and Bishop score<6, consented to participate in the study. Fifty-one of the cases were included in misoprostol group and a 100 µg misoprostol tablet was placed in the posterior vaginal fornix. Another 51 cases were included in oxytocin group. Labor characteristics, maternal and neonatal outcome were analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202018897N1**
Registration date: **2012-03-07, 1390/12/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-03-07, 1390/12/17

Registrant information

Name

Safoura Rouholamin

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2008-12-21, 1387/10/01

Expected recruitment end date

2009-08-21, 1388/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of vaginal misoprostol tablet and oxytocin in induction of labor at term pregnancy

Public title

Effect of misoprostol on labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: singleton live pregnancy at term(GA≥ 37week) in the cephalic presentation; absent of active labor; unfavorable cervix(Bishop scor≤6) and normal fetal heart rate tracing. Exclusion criteria: known cephalopelvic disproportion; abnormal presentation; previous cesarean delivery or other type of uterine surgery; cervical cancer; fetal macrosomia; active herpes

genitalia; multiparity and fetal anomaly.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice chancellor-Isfahan university of medical science

Street address
Pol felezi,motahari st. shahid beheshti hospital

City
Isfahan

Postal code
8184851153

Approval date
2008-11-05, 1387/08/15

Ethics committee reference number
387303

Health conditions studied

1

Description of health condition studied
Efficacy on induction of labor

ICD-10 code
O61.0

ICD-10 code description
Failed medical induction of labour

Primary outcomes

1

Description
Interval from induction to true labor

Timepoint
Vaginal exam for evaluation of dilatation and effacment

Method of measurement
By vaginal exam

2

Description
Interval from true labor to delivery

Timepoint
Vaginal exam for evaluation of dilatation and effacment q 1 hour

Method of measurement
By vaginal exam

3

Description
Interval from induction to delivery

Timepoint
Vaginal exam for evaluation of dilatation and effacment q 1 hour

Method of measurement
By vaginal exam

Secondary outcomes

1

Description
Rate of vaginal delivery

Timepoint
At delivery time and 48 hours afterthat

Method of measurement
By clinical evaluation and add to form

2

Description
Post partum complication

Timepoint
At delivery time and 48 hours afterthat

Method of measurement
By clinical evaluation and add to form

3

Description
Neonatal outcom

Timepoint
At delivery time and 48 hours afterthat

Method of measurement
By clinical evaluation and add to form

Intervention groups

1

Description
Insertion of 100 microgram vaginal misoprostol

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid beheshti hospital
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Faculty of Medicine
Full name of responsible person
Vice chancellor for research, Isfahan university of medical science
Street address
Isfahan medical university, hezarjreeb street
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Faculty of Medicine
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
Faculty of medicin
Full name of responsible person
Dr.Rouholamin safoura
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Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of medicine (Isfahan medical university)
Full name of responsible person
Dr. zahra allameh
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Other areas of specialty/work
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Beheshti hospital
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Isfahan
Postal code
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+91 33159672
Fax
Email
z_allameh@med.mui.ac.ir
Web page address

Person responsible for updating data

Contact

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