

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 \geq 37week) in the cephalic presentation; absent of active labor; unfavorable cervix(Bishop scor \leq 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 effacement

Method of measurement

By vaginal exam

2

Description

Interval from true labor to delivery

Timepoint

Vaginal exam for evaluation of dilatation and effacement
q 1 hour

Method of measurement

By vaginal exam

3

Description

Interval from induction to delivery

Timepoint

Vaginal exam for evaluation of dilatation and effacement
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 medicine

Full name of responsible person

Dr.Rouholamin safoura

Position

Assistant professor

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of medicine (Isfahan medical university)

Full name of responsible person

Dr. zahra allameh

Position

Associate professor

Other areas of specialty/work

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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