

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparison between the effect of oral titrated solution of misoprostol and intravenous oxitocine for labor induction in term pregnancies.

Protocol summary

Summary

Objective: A comparison between the effect of oral titrated misoprostol and intravenous oxitocine for labor induction in term pregnancies. Design: Randomized clinical trial Setting and conduct: Double blind Participants: Inclusion criteria: age between 20-40 year old; reliable gestational age between 40-42 weeks; singleton pregnancy with cephalic presentation; BISHOP Score of more than 5; favorable pelvis. Exclusion criteria: parity of more than 3, blood pressure equal or more than 160/110 mmHg; abnormal NST and any sign of fetal distress; urine protein of more than 2 gram in 24 hours; suspicious for HELLP syndrome; poly hydramnios; probable macrosomia; any vaginal bleeding; history of any surgery on uterus; prostaglandin use during present pregnancy and beginning of spontaneous uterine contractions. Intervention: prescription of titrated oral misoprostol in one group and oxitocine in the other group. Main outcome: number of deliveries during the first 24 hours. Other outcomes: number of deliveries during 6-12-18 hours from the beginning of induction; duration of stage 1 , 2 and 3 of labor; interval between the beginning of induction up to the beginning of suitable contractions(3 forceful contractions during 10 minutes); hyper stimulation; number of vaginal deliveries , instrumental deliveries and cesarean sections; indications for cesarean deliveries; fetal distress; neonatal Apgar Score; NICU admission; and duration of hospital stay for mother and baby.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403242624N13**

Registration date: **2014-09-09, 1393/06/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-09, 1393/06/18

Registrant information

Name

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 3487

Email address

maryamka@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator.

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the effect of oral titrated solution of misoprostol and intravenous oxitocine for labor induction in term pregnancies.

Public title

Labor induction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 20-40 year old; reliable gestational age between 40-42 weeks; singleton pregnancy with cephalic presentation; BISHOP Score of more than 5; favorable pelvis. Exclusion criteria: parity of more than 3, blood pressure equal or more than 160/110 mmHg; abnormal NST and any sign of fetal distress; urine protein of more than 2 gram in 24 hours; suspicious for HELLP syndrome; poly hydramnios; probable macrosomia; any vaginal bleeding; history of any surgery on uterus; prostaglandin use during present pregnancy and beginning of spontaneous uterine contractions.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic comittee of Iran University of Medical Sciences

Street address

Hemmat highway, Chamran Cross

City

Tehran

Postal code

16117

Approval date

2014-07-28, 1393/05/06

Ethics committee reference number

93/2129 /105/5

Health conditions studied

1

Description of health condition studied

cervical ripening

ICD-10 code

O30

ICD-10 code description

Maternal care related to the fetus and amniotic cavity and possible delivery problems

2

Description of health condition studied

induction of labor

ICD-10 code

O61

ICD-10 code description

Complications of labour and delivery.

3

Description of health condition studied

medical induction of labour

ICD-10 code

O61.0

ICD-10 code description

Failed medical induction of labour

4

Description of health condition studied

Delivery

ICD-10 code

O80

ICD-10 code description

Delivery

Primary outcomes

1

Description

Number of deliveries during the first 24 hours.

Timepoint

24 hours

Method of measurement

Data sheets

Secondary outcomes

1

Description

rount of delivery

Timepoint

Method of measurement

data sheets

2

Description

uterine hyperstimulation

Timepoint

every 30 minutes

Method of measurement

monitoring of uterine contractions- tocography

3**Description**

fetal distress

Timepoint

every 15 minutes

Method of measurement

fetal heart rate monitoring with tococardiography

4**Description**

neonatal Apgar Score

Timepoint

minute 1 and 5

Method of measurement

data sheets

5**Description**

number of deliveries during 6-12-18 hours from the beginning of induction

Timepoint

6-12-18 hours from the beginning of induction

Method of measurement

data sheets

6**Description**

duration of stage 1 , 2 and 3 of labor.

Timepoint

end of stage 1 , 2 and 3 of labor

Method of measurement

data sheets

7**Description**

interval between the beginning of induction up to the beginning of suitable contractions(3 forceful contractions during 10 minutes).

Timepoint

every 30 minutes

Method of measurement

data sheets

8**Description**

indications for cesarean deliveries.

Timepoint

during cesarean deliveries

Method of measurement

data sheets

9**Description**

NICU admission

Timepoint

After birth up to discharge.

Method of measurement

data sheets

10**Description**

duration of hospital stay for mother and baby

Timepoint

admission , discharge.

Method of measurement

data sheets

Intervention groups**1****Description**

administration of oral titrated solution of misoprostol. 200 microgram misoprostol will be solved in 200 mili liter water, and 20 cc of this solution will be prescribed every 2 hours. (maximum 60 micro gram).

Category

Treatment - Drugs

2**Description**

infusion of 2.5 mili units oxytocine per minute that will be doubled every 15 minutes. Maximum dose of oxytocine is 60 mili units per minute.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Akbarabadi Teaching Hospital

Full name of responsible person

Maryam Kashanian

Street address

Molavi avenue, Molavi Cross.

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research ,Iran University of Medical Sciences.

Full name of responsible person

Dr Seyed Javad Mousavi

Street address

Hemmat High way, Chamran Cross.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research ,Iran University of Medical Sciences.

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

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

Professor.

Other areas of specialty/work

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Position

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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