Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 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
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Iran (Islamic Republic of)
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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/د

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
rout 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 oxitocine per minute that will be doubled every 15 minutes. Maximum dose of oxitocine 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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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