Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

A comparison between the effects of oral titrated suspension of misoprostol and infusion of oxytocin for labor induction in term pregnancies.

Protocol summary

Summary

Objectives: Comparison between the effects of oral titrated suspension of misoprostol and infusion of oxytocin for labor induction in term pregnancies. Design: Randomized clinical trial. Setting and conduct: In misoprostol group, mioprostol (synthetic prostaglandin E1 analogue) suspension (Cytotec, 200 micro-gram tablet will be solved in 200 cc of distilled water), will be administered in 20 micro-gram dosages; (20 milliliter) every 2 hours for 3 doses (total of 60 µg). Uterine contractions will be monitored during this period. If contractions are appropriate (=>3 forceful contractions with a duration of 40 seconds in 10 minutes), drug administration will be terminated. In case of inappropriate contractions, and reassuring FHR, misoprostol will be increased up to 40 µg every 2 hours until having appropriate contractions and then, administration of misoprostole will be terminated. In this group, serum with distilled water will be used for blinding the study similar to the oxitocin group. In oxytocin group, intravenous oxytocin will be infused in a dosage of 2.5 mIU per minute and will be doubled every 15 minutes until having appropriate contractions. Maximum dosage of oxytocin is 60 mIU per minute. In this group, water will be used for blinding the study similar to the misoprostole group. Participants: Inclusion criteria includes: maternal age between 20-40 years; certain gestational age between 40-42 weeks; singleton with cephalic presentation; Bishop Score of more than 5 and favorable pelvis in vaginal examination. Exclusion criteria includes: parity of more than 3; high risk pregnancy; using prostaglandins during present pregnancy and spontaneous labor. Interventions: administration of oral titrated solution of misoprostol and infusion of oxytocin. Main outcome: Number of deliveries during the first 24 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602102624N19**
Registration date: **2016-04-05, 1395/01/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-05, 1395/01/17

Registrant information

Name

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator.

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A comparison between the effects of oral titrated suspension of misoprostol and infusion of oxytocin for labor induction in term pregnancies.

Public title
Labor induction with oxytocin and misoprostol.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria includes: maternal age between 20-40 years; certain gestational age between 40-42 weeks; singleton with cephalic presentation; Bishop Score of more than 5 and favorable pelvis in vaginal examination. Exclusion criteria includes: parity of more than 3; blood pressure of equal or/and more than 160/110, non reassuring NST or any evidence of fetal distress; proteinuria of more than 2 grams; suspicion to HELLP syndrome; poly-hydramnios; probable macrosomia; any vaginal bleeding more than bloody show; history of any surgical operation on the uterus; using prostaglandins during present pregnancy and spontaneous labor.
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)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization was performed as stratified block randomization.

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
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
Labor and delivery
ICD-10 code
080
ICD-10 code description
Delivery

2

Description of health condition studied
Labor and delivery
ICD-10 code
080.0
ICD-10 code description
Spontaneous vertex delivery

3

Description of health condition studied
Labor and delivery
ICD-10 code
080.9
ICD-10 code description
Single spontaneous delivery, unspecified

4

Description of health condition studied
Labor and delivery
ICD-10 code
082
ICD-10 code description
Single delivery by caesarean section

5

Description of health condition studied
Labor and delivery
ICD-10 code
082.1
ICD-10 code description
Delivery by emergency caesarean section

Primary outcomes

1

Description
Delivery during first 24 hours of induction of labor
Timepoint
24 hours

Method of measurement
Questionnaire

Secondary outcomes

1

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
Questionnaire

2

Description
Duration of stage 1 , 2 and 3 of labor.
Timepoint
After birth
Method of measurement
Questionnaire

3

Description
Interval between the beginning of induction up to the beginning of suitable contractions(3 forceful contractions during 10 minutes).
Timepoint
Beginning of suitable contractions
Method of measurement
Questionnaire

4

Description
Uterine tachysystole
Timepoint
During labor
Method of measurement
Questionnaire

5

Description
Number of vaginal deliveries and instrumental and cesarean deliveries
Timepoint
After birth
Method of measurement
Data sheets

6

Description
Indications for cesarean deliveries.
Timepoint
After birth
Method of measurement
Data sheets

7

Description
Fetal distress
Timepoint
During labor and fatal monitoring
Method of measurement
Questionnaire

8

Description
Neonatal Apgar Score
Timepoint
After birth
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
After birth up to discharge.
Method of measurement
Data sheets

Intervention groups

1

Description
Intervention group: Administration of oral misoprostol
Category
Treatment - Drugs

2

Description
Infusion of oxytocin
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 Ali 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
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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