Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the Effect of Oral Misoprostol and Intravenous Oxytocin on Labor Induction in pregnant women

Protocol summary

Study aim
Comparing the Effect of Oral Misoprostol and Intravenous Oxytocin on Labor Induction

Design
A randomized, double blind, parallel clinical trial including 130 patients with postdate pregnancy receiving two intervention for induction of labor. The patients, intervention appliers and outcome assessors will be blinded toward the study groups.

Settings and conduct
A university hospital affiliated with Fasa University of Medical Sciences. The drugs would be prepared in pharmacology department in dark syringes and uniform tablets and would be provided to the physician and caring nurse blindly. Those recording the outcome will also be blinded toward the study groups.

Participants/Inclusion and exclusion criteria
We included women over 18 years old, singleton pregnancy, cervical closure (Bishop score greater than six), first and second pregnancy. We excluded those with multiple pregnancy, emergency cesarean section and maternal sensitivity to oxytocin, misoprostol and prostagalandin analogues.

Intervention groups
Patients in case group will receive 10 units of intravenous oxytocin for labor induction. Patients in control group will receive 50 mg oral Misoprostol every 4 hours for 2 days maximally.

Main outcome variables
Successful delivery within 48 hours after intervention Route of delivery (Cesarean delivery vs Natural Vaginal delivery) Frequency of uterine contractions per hour Drug adverse effects Apgar at 1- and 5-min

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171111037374N1**
Registration date: **2018-07-03, 1397/04/12**
Registration timing: **retrospective**

Last update: **2018-07-03, 1397/04/12**
Update count: **0**

Registration date
2018-07-03, 1397/04/12

Registrant information

Name
Hadi Zare Marzouni

Name of organization / entity

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Iran (Islamic Republic of)

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+98 911 861 2103

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zaremh931@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-22, 1396/10/01

Expected recruitment end date
2018-03-26, 1397/01/06

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the Effect of Oral Misoprostol and Intravenous Oxytocin on Labor Induction in pregnant women

Public title
Comparing the Effect of Oral Misoprostol and Intravenous

Oxytocin on Labor Induction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age more than 42 weeks first and second pregnancy women over 18 years old singleton pregnancy, cervical closure (Bishop score greater than six)

Exclusion criteria:

Multiple pregnancies need for immediate cesarean section history of uterine scarring placenta previa vaginal bleeding more than normal postpartum bleeding heart, liver and kidney diseases history of sensitivity to Oxytocin, Misoprostol or prostaglandin analogues severe congenital anomalies in the fetus.

Age

From **18 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

The included patients were randomly assigned to 2 study groups using a computer-based random digit generator utilizing the admission numbers

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are unaware of being present in the case and control group. Also outcome assessor and data analyser will be blind

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Fasa University of Medical Sciences

Street address

Ebne Sina Square

City

Fasa

Province

Fars

Postal code

7461686688

Approval date

2017-09-05, 1396/06/14

Ethics committee reference number

IR.FUMS.REC.1396.222

Health conditions studied

1

Description of health condition studied

Abdominal pregnancy

ICD-10 code

O00.0

ICD-10 code description

Abdominal pregnancy

2

Description of health condition studied

(Induced) termination of pregnancy with other and unspecified complications

ICD-10 code

O04.8

ICD-10 code description

(Induced) termination of pregnancy with other and unspecified complications

Primary outcomes

1

Description

Delivery withing 48 hours after intervention

Timepoint

48 hours after intervention

Method of measurement

Recording the number of patients with successful delivery within 48 hours

2

Description

Route of delivery

Timepoint

At time if delivery

Method of measurement

Recording the route of delivery (Cesarean or vaginal delivery)

3

Description

Neonatal Apgar

Timepoint

1 and 5 minutes after birth

Method of measurement

Apgar

Secondary outcomes

1

Description
Adverse Effects
Timepoint
1, 2, 4, 8 and 10 days after intervention
Method of measurement
Adverse drug effects form

Intervention groups

1

Description
Intervention group: 50 micrograms of oral misoprostol for induction of labor. If no appropriate uterine contractions were observed, patients received 50 mg Misoprostol every four hours and finally twice a day. Intravenous placebo was also received in the case group.
Category
Treatment - Drugs

2

Description
Control group: 10 units of Oxytocin dissolved in 1000 cc of dextrose 5% for labor induction. This group also received oral placebo tablets at the same time.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Educational hospital of Fasa University of Medical Science, Fasa, Iran
Full name of responsible person
Roya Kokabi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fasa University of Medical Sciences
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Mojtaba Farjam
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Fasa University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Roya Kokabi
Position
Assistant professor
Latest degree
Specialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
After the end of the project and the collection of information, the results are published as an article.

When the data will become available and for how long
The results will available 6 months after the publication

To whom data/document is available
The findings will be available to the public, researchers and clinicians.

Under which criteria data/document could be used
All data on which non-personally identifiable data is sampled are available.

From where data/document is obtainable
Applicants can receive information from the article. In addition, they can answer their questions from Corresponding Author by e-mail.

What processes are involved for a request to access data/document
Applicants can receive information from the article. In addition, they can answer their questions from Corresponding Author by e-mail.

Comments