Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effect of misoprostol and oxytocin for the induction of labor in order to terminate pregnancy on maternal and fetal factors in pregnant women.

Protocol summary

Study aim

Comparison of the effect of misoprostol with oxytocin for labor Stimulations with physiological delivery control group, for termination of pregnancy on maternal and fetal factors.

Design

This randomized study with Parallel groups will be conducted on 90 primiparous pregnant women. Patients will randomly be divided into 3 groups by intra-envelope numbers. First intervention group: As the control group for performing physiological delivery Are considered. Second intervention group: receive misoprostol at a dose of 25 micrograms during delivery. Third intervention group receive oxytocin at a dose of 2 mlU / min during delivery.

Settings and conduct

This randomized study will be conducted in pregnant women referred to the Motahari Hospital of Jahrom. Patients who have criteria for entering the study by intra-envelope numbers will be divided into three groups And Average score of Apgar in the three groups will be examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant pregnant women ages 20-35 years، Women with a pregnancy term> 37 weeks، Lack of contraindication for normal delivery، Lack of drug sensitivity to Misoprostol and oxytocin. exclusion criteria: Limit of fetal growth،Suspected of fetal abnormality.

Intervention groups

First intervention group: As the control group, the physiological delivery is considered. Second intervention group: receive misoprostol at a dose of 25 micrograms during delivery. Third intervention group: receive oxytocin at a dose of 2 mlU / min during delivery.

Main outcome variables

Frequency of fetal meconium excretion,Average score of Apgar

General information

Reason for update

Modification of sampling date; sampling date was after the date of clinical trial registration.

Acronym

IRCT registration information

IRCT registration number: **IRCT20150407021653N18**
Registration date: **2019-05-25, 1398/03/04**
Registration timing: **prospective**

Last update: **2020-12-29, 1399/10/09**
Update count: **1**

Registration date

2019-05-25, 1398/03/04

Registrant information

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Athar Rasekh Jahromi
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Jahrom University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of misoprostol and oxytocin for the induction of labor in order to terminate pregnancy on maternal and fetal factors in pregnant women.

Public title

Comparison of the effect of misoprostol and oxytocin on the induction of labor.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women aged 20-35 Women with a term of pregnancy> 37 weeks Lack of Contraindication for normal delivery Lack of drug sensitivity to misoprostol and oxytocin Lack of chronic diseases

Exclusion criteria:

Dissatisfaction of participants to attend the study Tearing membranes Limit of fetal growth

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation method will be performed by a sealed envelope, in which the number of the groups will be placed, and Participants in the study will be randomly divided into three groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jahrom University of Medical Sciences

Street address

Jahrom, Motahari Blvd. Pardis building

City

Jahrom

Province

Fars

Postal code

7414846199

Approval date

2019-01-16, 1397/10/26

Ethics committee reference number

IR.JUMS.REC.1397.106

Health conditions studied

1

Description of health condition studied

Effect of termination of pregnancy on maternal and fetal factors

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Frequency of fetal heart rate drop

Timepoint

End of labor after intervention

Method of measurement

By scoring the Apgar

2

Description

Average score of the Apgar

Timepoint

End of labor after intervention

Method of measurement

By scoring the Apgar

Secondary outcomes

1

Description

Length of latent phase of labor

Timepoint

From the beginning of labor pain to the end of labor

Method of measurement

In minutes

2

Description

Duration of active phase of labor

Timepoint

From the 5-3 cm cervical dilatation to the end of pregnancy

Method of measurement

In minutes

Intervention groups

1

Description
Control group: As the control group, the physiological delivery is considered.
Category
Treatment - Drugs

2

Description
Intervention group1: receive misoprostol at a dose of 25 micrograms، during delivery.
Category
Treatment - Drugs

3

Description
Intervention group2: receive oxytocin at a dose of 2 mIU / min، during delivery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari hospital
Full name of responsible person
Athar Rasekh Jahromi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jahrom University of Medical Sciences
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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
Jahrom 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
Jahrom University of Medical Sciences
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Athar Rasekh Jahromi
Position
Associate professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available