

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 mIU / min during delivery.

Settings and conduct

This randomized study will be conducted in pregnant women referred to the Motehary 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 mIU / 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

Name

Athar Rasekh Jahromi

Name of organization / entity

Jahrom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 5432 6602

Email address

a.rasekh@jums.ac.ir

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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Pardis building,Motahari Blvd.,Jahrom

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

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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

Full name of responsible person

Athar Rasekh Jahromi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Jahrom University of Medical Sciences

Full name of responsible person

Zahra Sonbole

Position

دانشجو

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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