

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of Oral Misoprostol Tablets and Oxytocin for the Induction of Labor in Premature Rupture of Membranes

Protocol summary

Study aim

Comparison of the efficacy of oral misoprostol and intravenous oxytocin in inducing labor in rupture of premature embryonic membranes

Design

The study will be a clinical trial involving 160 pregnant mothers who have ruptured premature embryonic membranes between 34 and 42 weeks of gestation and will be referred to Mahdiah Hospital. After definitive diagnosis of placental rupture in speculum or positive fern test, patients are randomly divided into two groups for induction of labor. The case group will be given 50 micrograms of misoprostol orally every 4 hours up to a maximum of 5 doses. In the control group, oral placebo and intravenous oxytocin in ringer serum will be administered at a dose of 2ml / min and will be performed every 2 minutes up to 40ml / min.

Settings and conduct

The study will be a clinical trial involving 160 pregnant mothers who have ruptured premature embryonic membranes between 34 and 42 weeks of gestation and will be referred to Mahdiah Hospital. After definitive diagnosis of placental rupture in speculum or positive fern test, patients are randomly divided into two groups for induction of labor.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Positive Fern test Gestational age between 34 and 42 weeks Single pregnancy Cephalic presentation

Intervention groups

Pregnant mothers who have ruptured premature embryonic membranes between 34 and 42 weeks of gestation, After definitive diagnosis of placental rupture in speculum or positive fern test, patients are randomly divided into two groups for induction of labor. The case group will be given of misoprostol orally . In the control group, will be given oral placebo and intravenous oxytocin.

Main outcome variables

Induction of labor with misoprostol, induction of oxytocin, first and fifth minute apgar, postpartum hemorrhage, complications of misoprostol

General information

Reason for update

Acronym

مقایسه اثر میزوپروستول خوراکی و اکسی توسین وریدی در القا زایمان

IRCT registration information

IRCT registration number: **IRCT20191014045106N1**

Registration date: **2020-02-19, 1398/11/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-19, 1398/11/30**

Update count: **0**

Registration date

2020-02-19, 1398/11/30

Registrant information

Name

maryam mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7748 3253

Email address

dr.maryam671@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Oral Misoprostol Tablets and Oxytocin for the Induction of Labor in Premature Rupture of Membranes

Public title

Comparison of Oral Misoprostol Tablets and Oxytocin for the Induction of Labor in Premature Rupture of Membranes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Definitive diagnosis of rupture of the sacrotuberous ligament on examination with speculum or positive fern test
Gestational age between 34 and 42 weeks
Cephalic presentation
Bishop score ≤ 5
Indication of vaginal termination of pregnancy
Parity less than five
Absence of active labor
Absence of active labor

Exclusion criteria:

The presence of any fetal heart rate abnormalities
A history of cesarean section or uterine scarring
Contraindications for vaginal delivery such as placenta previa
Known allergy to prostaglandin (skin manifestations, hives, rash, shortness of breath, cough, chest pain and blurred vision after previous prostaglandin use)
Estimated baby weight over 4 kg
Active labor means at least 3 contractions with sufficient force and duration of at least 40 seconds within 10 minutes.
Active cardiovascular disease, asthma, glaucoma
Vaginal bleeding

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

This study was a clinical trial involving 160 pregnant mothers, ranging from 34 to 42 week. Pregnancy is referred to premature rupture of the membrane and go to Mahdih Hospital. Will do, it will be done. cervical examination and Bishop score and description. It will be done. After definitive diagnosis of premature rupture of membrane on speculum or positive fern test, patients are randomly divided into two groups for induction of labor.

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**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Chamran highway, Tehran, Iran. 7th Floor, Bldg No.2 .

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2019-09-04, 1398/06/13

Ethics committee reference number

IR.SBMU.MSP.REC.1398.533

Health conditions studied**1****Description of health condition studied**

Labor in premature rupture of fetal protective membranes

ICD-10 code

Z00.12

ICD-10 code description

Encounter for routine child health examination

Primary outcomes**1****Description**

Age

Timepoint

Baseline

Method of measurement

questionnaire

2**Description**

Pregnancy age

Timepoint

Baseline

Method of measurement

questionnaire

3

Description

Delivery time

Timepoint

During delivery

Method of measurement

questionnaire

4

Description

First and fifth minute appgar

Timepoint

First and fifth minute

Method of measurement

Based on Appgar score determination by examiner

5

Description

Postpartum hemorrhage

Timepoint

Immediately after delivery

Method of measurement

View by examiner / Yes, No

6

Description

Excretion of neonatal meconium

Timepoint

After birth

Method of measurement

View by examiner / Yes, No

Secondary outcomes

1

Description

Side Effects Of Misoprostol

Timepoint

Postpartum

Method of measurement

Question about person / fever, nausea, Vomiting, diarrhea

Intervention groups

1

Description

Intervention group: The case group will be given 50 micrograms of misoprostol orally every 4 hours up to a maximum of 5 doses.

Category

Treatment - Drugs

2

Description

Control group: In the control group, oral placebo and

intravenous oxytocin in ringer serum will be started at a dose of 2mlu / min and will be performed every 2 minutes up to 40mlu / min.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Mahdieh Hospital

Full name of responsible person

Maryam Mohammadi

Street address

Boroujerdi Street

City

Tehran

Province

Tehran

Postal code

1234567890

Phone

+98 21 5506 2644

Email

dr.maryam671@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ashin Zarghi

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Mahdieh Hospital, Boroujerdi Street

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Mohammadi

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Mohammadi

Position

Medical resident

Latest degree

Medical doctor

Other areas of specialty/work

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

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Full name of responsible person

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Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

Comparison of Oral Misoprostol Tablets and Oxytocin for the Induction of Labor in Premature Rupture of Membranes, All of its results can be used to manage diseases.

When the data will become available and for how long

Access 5 months after the results are published

To whom data/document is available

Academic and scientific researchers

Under which criteria data/document could be used

Management and Medical Care

From where data/document is obtainable

Mahdieh Hospital or Shahid Beheshti University of Medical Sciences

What processes are involved for a request to access data/document

In a Written Letter to the Documentation Authorities of Mahdie Hospital of Shahid Beheshti Medical University

Comments