Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

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

Protocol summary

Study aim

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

Design

The study will be a clinical trial involving 160 pregnant mothers who have ruptured premature embryos membran between 34 and 42 weeks of gestation and will be referred to Mahdieh Hospital. After definitive diagnosis of splenic rupture in speculum or positive fren 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 2mlu / min and will be performed every 2 minutes up to 40mlu / min.

Settings and conduct

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

Participants/Inclusion and exclusion criteria

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

Intervention groups

Pregnant mothers who have ruptured premature embryos membran between 34 and 42 weeks of gestation, After definitive diagnosis of splenic rupture in speculum or positive fren 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 میزوپرستول 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 inPremature Rupture of Membranes

Public title
Comparison of Oral Misoprostol Tablets and Oxytocin for the Induction of Labor inPremature Rupture of Membranes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of rupture of the sachet on examination with speculum or positive frenne 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 peria 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 embryo and go to Mahdieh Hospital Will do, it will be done. cervical examination and Bishop score and description It will be done. After definitive diagnosis of splenic rupture in speculum or positive fren 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 apgar
Timepoint
First and fifth minute
Method of measurement
Based on Apgar 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
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1234567890
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+98 21 5506 2644
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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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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 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
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