Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of oral misoprostol and Intravenous oxytocin for induction of labor at Premature rupture of membrane in primigravida women

Protocol summary

Summary

The aim of this survey is comparison of oral Misoprostol versus intra venous oxytocin for cervical ripening in primiparous pregnant women with premature rupture of membrane. Those Primiparous pregnant women with premature rupture of membrane admitted in hospital between 36 to 42 weeks of pregnancy with inappropriate bishop score (less than 4). After written and informed consent to participate in the survey the women will be divided into two groups randomly, one group will be given 75 microgram of oral Misoprostol plus intra venous saline normal while another group intra venous oxytocin 2mlu/min increased 2 mlu/min any 10 minute plus oral placebo. Any person who involved as Executive agents in this study, have no information about prescribed drugs. Drug Doses will be repeated each 4 hour up to two times when it will be necessary. Fetal heart rate and uterus contractions will be checked before every dose prescription for about 10 minutes. Also vaginal examination will be done for every person before induction. In case of acquiring three contractions during ten minutes or reaching to active phase (at least 4cm dilatation) we won't give next dose. Finally we will compare these factors by using statistical methods: Time interval from labor induction beginning to active phase reaching, delivery type, vaginal delivery rate during first 12 hours, tachysystole and hyper stimulation, Apgar score, and 4 hours after induction bishop score, consumed dose of Misoprostol and maternal complication.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104131946N9**
Registration date: **2011-08-21, 1390/05/30**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2011-08-21, 1390/05/30

Registrant information

Name

Mandana Mansur Ghanaie

Name of organization / entity

Giulan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral misoprostol and Intravenous oxytocin for induction of labor at Premature rupture of membrane in primigravida women

Public title

Comparison of oral misoprostol and Intravenous oxytocin for induction of labor at Premature rupture of membrane

in primigravida women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: a) single pregnancy (between 36 to 42 weeks); b)vertex presentation; c)bishop score equal or less than four; d) absence of uterus spontaneous contractions;e)normal fetal heart rate; f) cephalopelvic proportion. Exclusion criteria: a) sensitivity to PGs; b) previous history of cesarean; c) uterus wall scar; d) preeclampsia or blood pressure more than 140/90 mmHg; e) history of heart disease ,asthma, glaucoma; f)IUGR; g)age under18 years

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee Guilan University of Medical Sciences

Street address

Vice Chancellor for research, Guilan University of Medical Sciences, Melat st, Namjoo Ave

City

Rasht

Postal code

0098

Approval date

2011-07-20, 1390/04/29

Ethics committee reference number

1900189604

Health conditions studied

1

Description of health condition studied

Pregnancy, childbirth and the puerperium

ICD-10 code

O74.8

ICD-10 code description

Other complications of anaesthesia during labour and delivery

Primary outcomes

1

Description

Comparison of oral misoprostol and Intravenous oxytocin

Timepoint

Every four hours up to two times

Method of measurement

Vaginal examination and record in Questionnaire

Secondary outcomes

1

Description

Determination of time interval from labor induction beginning to active phase reaching

Timepoint

Time recording of induction beginning and delivery

Method of measurement

Time recording of induction beginning and delivery in Questionnaire

2

Description

Delivery type frequency

Timepoint

After delivery

Method of measurement

Patients' medical document

3

Description

Vaginal delivery frequency during first 12 hours

Timepoint

After delivery

Method of measurement

Patients' medical document

4

Description

Tachysystole incidence

Timepoint

Time recording of induction beginning up to active phase

Method of measurement

Patients' medical document

5

Description
Hyper stimulation incidence
Timepoint
Time recording of induction beginning up to active phase
Method of measurement
Patients' medical document

6

Description
Fetal Heart Rate disorder
Timepoint
Time recording of induction beginning and delivery
Method of measurement
Patients' medical document

7

Description
Failure to progress frequency
Timepoint
Entering to active phase up to delivery
Method of measurement
Patients' medical document

8

Description
Determination of Bishop Score alteration average after 4 hours
Timepoint
After 4 hours from induction beginning
Method of measurement
Vaginal examination

9

Description
Determination of NICU admission rate
Timepoint
After delivery
Method of measurement
Patients' medical document

10

Description
APGAR score less than 7
Timepoint
After delivery
Method of measurement
Patients' medical document

11

Description
Frequency of maternal complication
Timepoint
Time recording of induction beginning and delivery
Method of measurement
Patients' medical document

Intervention groups

1

Description
Prescription of 75 microgram of oral Misoprostol plus intra venous normal saline
Category
Treatment - Drugs

2

Description
Prescription of intra venous oxytocin 2mlu/min increased 2 mlu/min any 10 minute.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Guilan University of Medical Sciences. Alzahra Hospital
Full name of responsible person
Dr. Mandana Mansur Ghanaie
Street address
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for researchr, Guilan University of Medical Sciences
Full name of responsible person
Dr. Abdolrasol Sobhani
Street address
Namjo street, Mellat street
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for researchr, Guilan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr. Mandana Mansur Ghanaie

Position

Accosiated professor of Obstetrics and Gynecology,

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Mandana Mansur Ghanaie

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Seyedeh Maryam Mousavi Chahardeh

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty