Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Aug 2026

Comparison of Sublingual and vaginal Misoprostol for labor induction in primiparous women

Protocol summary

Summary

The aim of this trial is to compare sublingual Misoprostol with vaginal Misoprostol for cervical ripening in primiparous pregnant women who have been candidats for labour induction. Those Primiparous pregnant women will be entered in this study who have been candidates for pregnancy termination between 36 to 42 weeks of pregnancy with inappropriate bishop score (less than 4). After written and informed consent to participate in the study the women will be divided into two groups randomly, one group will be given 25 microgram of sublingual Misoprostol plus vaginal placebo while another group will receive 50 microgram of vaginal Misoprostol plus sublingual placebo. All researchers who are involved in this study, have no information about type of intervention in the two groups. Drug Doses will be repeated every 4 hours up to four times if necessary. Fetal heart rate and uterus contractions will be checked before every dose prescription for about 10 minutes. Vaginal examination will be done for every person before induction. In case of acquiring three contractions during ten minutes or reaching the active phase (at least 4cm dilatation) we won't give the next dose. Finally we will compare the following factors by means of statistical methods: Time interval from labour induction till the active phase, delivery type, vaginal delivery rate during first 12 hours and also during first 12 to 24 hours, tachysystole and hyper stimulation, caesarean section rate, Apgar score, meconium discharge, and bishop score 4 hours after induction, consumed dose of Misoprostol and Oxytocine in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903121096N3**
Registration date: **2010-06-02, 1389/03/12**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2010-06-02, 1389/03/12

Registrant information

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Name of organization / entity
Guilan University of Medical Science
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research – Guilan university of medical sciences

Expected recruitment start date

2010-07-23, 1389/05/01

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Sublingual and vaginal Misoprostol for labor induction in primiparous women

Public title

Effect of sublingual Misoprostol versus vaginal Misoprostol in labor induction success.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: a) single pregnancy (between 36 to 42 weeks), b) vertex presentation, c) intact fetal membrane, d) bishop score equal or less than four e) absence of uterus spontaneous contractions f) fetal weight less than 4000gr j) normal fetal heart rate h) 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) PROM f) vaginal bleeding

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **126**

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

Vice Chancellor for research , Guilan university of medical sciences

Street address

Namjoo street, Vice Chancellor for research , Guilan university of medical sciences

City

Rasht

Postal code

Approval date

empty

Ethics committee reference number

1694

Health conditions studied

1

Description of health condition studied

labour induction

ICD-10 code

O62.3

ICD-10 code description

Precipitate labour

Primary outcomes

1

Description

Time interval from labour induction to delivery

Timepoint

After delivery

Method of measurement

Time recording of induction beginning and delivery in Questionnaire

2

Description

Delivery type frequency

Timepoint

After delivery

Method of measurement

patient medical document

3

Description

Dose amount

Timepoint

Four hours after last prescription of Misoprostol up to delivery time

Method of measurement

Patient medical document

Secondary outcomes

1

Description

Vaginal delivery frequency during first 12 hours

Timepoint

During 12 hours from induction beginning

Method of measurement

Patient medical document

2

Description

Vaginal delivery frequency during first 12 to 24 hours

Timepoint

During 12 to 24 hours from induction beginning

Method of measurement

Patient medical document

3

Description

Tachysystole incidence rate

Timepoint

Every 4 hours until entering in active phase

Method of measurement

Fetal heart monitoring device and recording of uterus contractions

4

Description

Hyper stimulation incidence rate

Timepoint

Every 4 hours until entering in active phase

Method of measurement

Fetal heart monitoring device and recording of uterus contractions

5

Description

Cesarean rate due to FHR disorder

Timepoint

After cesarean

Method of measurement

patient medical document

6

Description

Cesarean section rate due to delivery failure

Timepoint

After cesarean section

Method of measurement

Patient medical document

7

Description

Apgar score below 7 rate

Timepoint

After delivery

Method of measurement

Patient medical document

8

Description

Meconium discharge rate

Timepoint

By presenting 3cm or more dilatation after rupture of membrance

Method of measurement

Clinical examination or patient medical document

9

Description

NICU admission rate

Timepoint

After delivery

Method of measurement

Patient medical document

10

Description

Bishop score alteration average after 4 hours

Timepoint

After 4 hours from beginning of induction

Method of measurement

Vaginal examination

Intervention groups

1

Description

Prescription of 25 microgram of sublingual Misoprostol plus vaginal placebo every four hours up to four times.

Category

Treatment - Drugs

2

Description

Prescription of 50 microgram of vaginal Misoprostol plus sublingual placebo every four hours up to four times.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Guilan university of medical sciences.Alzahra Hospital

Full name of responsible person

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research -Guilan university of medical sciences

Full name of responsible person

Dr.Abdolrasol Sobhani

Street address

Namjo street, Vice chancellor for research , Guilan University of Medical Sciences

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 research -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
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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