Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The Effects of vaginal Misoprostol, Laminaria and Isosorbide Dinitrate on cervical ripening before labor induction among the term parturients

Protocol summary

Summary

This study aimed to compare the effects of Misoprostol, Laminaria, and Isosorbide Dinitrate on cervical ripening. This randomised double blind clinical trial conduct at Shahidan Mombini Teaching Hospital of Sabzevar, Iran on 96 singleton term pregnant women with Bishop score less than 6. Women with rupture of membranes, severe Preeclampsia and noncephalic presentation are excluded. Participants were randomly divide into three groups of 25 microgram vaginal Misoprostol each 6 hours up to 2 doses, single dose Laminaria , and 40 milligram vaginal Isosorbide Dinitrate each 4 hours up to 3 doses.Administration of low dose Oxytocin immediately after preparation of the cervix or no response to procedures will be performed after 12 hours. The following parameters record and compare between the study groups:interval between cervical ripening and active phase of labor and delivery, mode of delivery, necessity of induction, and maternal and neonatal complications

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050527643N2**
Registration date: **2016-05-23, 1395/03/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-23, 1395/03/03

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Sabzevar University Of Medical Sciences

Expected recruitment start date

2016-05-17, 1395/02/28

Expected recruitment end date

2017-05-18, 1396/02/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of vaginal Misoprostol, Laminaria and Isosorbide Dinitrate on cervical ripening before labor induction among the term parturients

Public title

cervical ripening and termination of term pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:term pregnancy ; bishop score less than 6 ; cephalic presentation ; singleton pregnancy Exclusion criteria:use of another way for cervical ripenig ; contraindication of labor inducton or NVD ; mother's comorbidity ; rupture of fetus membrane ; severe preeclampsia ; vaginal bleeding ; Placenta previa ; having a spontaneous contraction

Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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 Sabzevar University of Medical Sciences
Street address
Sabzevar University of Medical Sciences, Asadabadi St
City
Sabzevar
Postal code
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
Medsab.Rec.1394.3

Health conditions studied

1

Description of health condition studied
vaginal delivery
ICD-10 code
O80.0
ICD-10 code description
Spontaneous vertex delivery

Primary outcomes

1

Description
Cervical ripening
Timepoint
On admissiom and 12 hours later and before insertion of each dose
Method of measurement
Vaginal exam based on Bishop score

Secondary outcomes

1

Description
Maternal complications (Over stimulation of the uterus, headaches, tachycardia, hypotension, nausea, vomiting, and dizziness)
Timepoint
During at the intervention
Method of measurement
Observation and Examination

2

Description
Method of delivery
Timepoint
During at the intervention
Method of measurement
Observation and Examination

3

Description
Duration of the first stage of labor
Timepoint
Active stage of labor
Method of measurement
Hour

4

Description
Neonatal outcomes (Apgar score at first and fifth minutes, birth weight, hospitalization of neonate in the Neonatal Intensive Care Unit)
Timepoint
During at the intervention
Method of measurement
Observation and Examination

5

Description
Necessity of induction
Timepoint
During at the intervention
Method of measurement
Observation and Examination

Intervention groups

1

Description
in the first group, Misoprostol, 25 microgram of this drug as oral Tablet will insert in posterior fornix of vagina.The dose can be repeated up to 2 times every 6 hours. The second doses, if Bishop score is less than 8 per examination will be repeated every 6 hours. Administration of low dose Oxytocin immediately after preparation of the cervix (active phase of labor with utrine contracture less than 3 in 10 minutes) or no response to procedures will be performed after 12 hours.

Category
Treatment - Drugs

2

Description
in the second group, Isosorbide Dinitrate, 40 milligram of this drug as Oral Tablets will insert to the mother's vagina in Posterior Fornix. The dose can be repeated up to 3 times every 4 hours. The second and third doses, if Bishop is less than 8 will be repeated every 4 hours. Administration of low dose Oxytocin immediately after preparation of the cervix (active phase of labor with utrine contracture less than 3 in 10 minutes) or no response to procedures will be performed after 12 hours.

Category
Treatment - Drugs

3

Description
In third group, first, maternal vagina will be cleaned with Bethadine. After the Speculum inserted, the anterior lip of the Cervix will be taken with Tenaculum and Laminaria will be taken down depending on the size of the cervix so that its tip has been diced near the internal opening of the cervix.Then after 12 hours Laminara will be taken out. Administration of low dose Oxytocin immediately after preparation of the cervix (active phase of labor with utrine contracture less than 3 in 10 minutes) or no response to procedures will be performed after 12 hours.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahidan Mobini Hospital
Full name of responsible person
Sima Haeri
Street address
Mobini Hospital, Kashefi St, Sabzevar
City
Sabzevar

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Sabzevar University of Medical Sciences
Full name of responsible person
Mohammad Mohammadzadeh
Street address
Deputy of Research and Technology, Sabzevar University of Medical Sciences
City
Sabzevar
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 of Sabzevar 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
Sabzevar University of Medical Sciences
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Behnaz Sovizi

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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