Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

vaginal misoprostol versus laminaria for cervical ripeing in full term pregnants. A comparative randomized trial

Protocol summary

Summary

This is a prospective randomized double blinded study to compare Laminaria and misoprostol in cervical ripening for induction of labor. Study participants are 100 pregnant women, 18 to 45 years old that randomly divide into two equal groups, 1 (Misoprostol) and 2(Laminaria). Both drugs are used in patients with unfavorable cervix (0-2 centimeters dilatation and 0-30% effacement). Patients on admission, 6 hours later and then every 2 hours undergo vaginal examination. Person who will perform the first exam and use the drug is different with someone who would do next exams. Second examiner and also the patients are not aware of the type of the drug. Women With rupture of membranes, severe preeclampsia, intrauterine growth restriction and non-cephalic presentation are excluded. Misoprostol, 25 microgram suppositories, are applied intravaginally in posterior fornix. After 6 hours second dose is repeated if dilatation change does not occur. Laminaria is placed into the cervix intravaginally and it will be removed after 6 hours by first examiner and it is used also in one dose. In cases of 2-3 Centimeters dilatation, labor will be continued otherwise, oxytocin is used in both groups. Induction-to-delivery interval, fetal distress, cesarean sections rate, tick meconium and uterine hyperstimulation will be examined in both groups of the study. Finally, results will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010712037N1**
Registration date: **2013-01-23, 1391/11/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-01-23, 1391/11/04

Registrant information

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Jamileh Nezamzavareh
Name of organization / entity
Kashan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2012-09-15, 1391/06/25

Expected recruitment end date

2013-04-14, 1392/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

vaginal misoprostol versus laminaria for cervical ripeing in full term pregnants. A comparative randomized trial

Public title

vaginal misoprostol versus laminaria for cervical ripeing in full term pregnants. A comparative randomized trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: single pregnants with unriped cervix.

Exclusion criteria: noncephalic presentation; sever preeclampsia; intrauterine growth restriction(IUGR); presence of uterine contractions; fetal distress; oligohydramnios and rupture of fetal membranes.

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

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
Kashan University of Medical Sciences

Street address
Ghotb-e ravandi Blvd.

City
Kashan

Postal code
/8715988141

Approval date
2012-09-11, 1391/06/21

Ethics committee reference number
2272/1/5/29/پ

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
Dilatation of cervix

Timepoint
On admission, 6 hours later and then every 2 hours

Method of measurement
Vaginal exam based on Bishop Score

2

Description
Induction to delivery time

Timepoint
Since induction of labor to delivery

Method of measurement
Calculating time(hour)

Secondary outcomes

1

Description
Fetal distress

Timepoint
Every 15 minutes

Method of measurement
Auscultation of fetal heart

2

Description
Thick meconium

Timepoint
Time of membrane rupture

Method of measurement
Vaginal examination

Intervention groups

1

Description
Intervention Group: vaginal administration of laminaria (one dose) at onset of the labor induction

Category
Treatment - Drugs

2

Description
Control group: Vaginal administration of misoprostol 25 mcg (1dose) at the onset of induction of labor and if needed, the second dose administration of 25 mcg 6 hours after initial dose

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashan Shabih Khani Hospital
Full name of responsible person
Jamileh Nezam Zavareh
Street address
Shahid Beheshti street
City
Kashan

2

Recruitment center
Name of recruitment center
Kashan Beheshti Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Gholam Ali Hamidi
Street address
5th Kilometer Ghotbe Ravandi Bulv.
City
kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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

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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