

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### vaginal misoprostol versus laminaria for cervical ripening in full term pregnant. 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

###### Name

Jamileh Nezamzavareh

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1445 7233

###### Email address

nezamzavareh@kaums.ac.ir

##### 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 ripening in full term pregnant. A comparative randomized trial

##### Public title

vaginal misoprostol versus laminaria for cervical ripening in full term pregnant. A comparative randomized trial

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criterion: single pregnant with unripen cervix.

Exclusion criteria: noncephalic presentation; severe 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**

Jamileh Nezam Zavareh

**Street address**

Ghotb-e ravandi Blvd.

**City**

Kashan

## 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

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Jamileh Nezam Zavareh

**Position**

Resident of Gynecology and Obstetrics

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Mitra Behrashi

**Position**

Specialist in Gynecology and Obstetrics

**Other areas of specialty/work**

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## Person responsible for updating data

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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*