

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison of intravaginal misoprostol, seaweed Laminaria and Foley catheter for cervical ripening and induction of labor in term pregnant women

Protocol summary

Study aim

Objective: The aim of this study is the comparison of intravaginal misoprostol, seaweed Laminaria and Foley catheter for cervical ripening and induction of labor in term pregnant women.

Design

Study design: Randomized double-blind clinical trial. Randomization will be done by the use of computer-generated random numbers.

Settings and conduct

Among term pregnant women with unripe cervix referred to Shabihkhani Clinic affiliated to Kashan University of Medical Sciences, 195 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged 18 to 45 years with unripe cervix, Gestational age ≥ 37 , Amniotic Fluid Index ≥ 5 , and Bishop Score < 5 . Exclusion criteria: Pregnant women with labor pain, patients develop chorioamnionitis, fever, and hemorrhage.

Intervention groups

Patients who enroll in the study will be randomized into one of 3 study arms: Intravaginal misoprostol (n=65), seaweed Laminaria (n=65), and Foley catheter (n=65) for cervical ripening and induction of labor in term pregnant women.

Main outcome variables

Outcomes: Bishop Scores and cervical dilatation (primary outcomes) and induction time to active phase of labor, induction time to delivery time, cesarean frequency rate and intrapartum complications (secondary outcomes) will be quantified.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N39**

Registration date: **2018-10-21, 1397/07/29**

Registration timing: **retrospective**

Last update: **2018-10-21, 1397/07/29**

Update count: **0**

Registration date

2018-10-21, 1397/07/29

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-29, 1397/03/08

Expected recruitment end date

2018-06-12, 1397/03/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravaginal misoprostol, seaweed Laminaria and Foley catheter for cervical ripening and induction of labor in term pregnant women

Public title

Comparison of intravaginal misoprostol, seaweed Laminaria and Foley catheter in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women aged 18 to 45 years with with unripe cervix Gestational age ≥ 37 Amniotic Fluid Index ≥ 5 Bishop Score < 5

Exclusion criteria:

Pregnant women with labor pain patients develop chorioamnionitis fever hemorrhage

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **195**

Randomization (investigator's opinion)

Randomized

Randomization description

To decrease potential confounding effects, all participants will have stratified randomization according to age and other characteristics. Then, participants in each block will be randomly allocated into three intervention groups. Randomization will be done by the use of computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Shabihkhani clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants into three groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Approval date

2018-05-28, 1397/03/07

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.012

Health conditions studied

1

Description of health condition studied

Pregnant state

ICD-10 code

Z33

ICD-10 code description

Pregnant state

Primary outcomes

1

Description

Bishop Scores

Timepoint

six hours after the intervention

Method of measurement

Physical Examination

2

Description

cervical dilatation

Timepoint

six hours after the intervention

Method of measurement

Physical Examination

Secondary outcomes

1

Description

induction time to active phase of labor

Timepoint

after the intervention

Method of measurement

time measurement (hours)

2

Description

induction time to delivery time

Timepoint

after the intervention

Method of measurement

time measurement (hours)

3

Description

cesarean frequency rate

Timepoint

after the intervention

Method of measurement

checklist

4

Description

intrapartum complications (Placental Abruption, atonia, and etc)

Timepoint

after the intervention

Method of measurement

physical examination

Intervention groups

1

Description

Intervention group: Intravaginal misoprostol 25 mcg (Cytotec, searle, England) will be put in posterior Culdusac for cervical ripening (n=65)

Category

Treatment - Drugs

2

Description

Intervention group: seaweed Laminaria (Dilateria™, Tasnimbehboud company, Tehran, Iran) will be used for cervical ripening (n=65)

Category

Treatment - Drugs

3

Description

Intervention group: An intra-cervical Foley catheter (size of 22) will be put intra-cervix with sterile condition for cervical ripening and it will be fixed by 15 ml liquid (n=65)

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shabihkhani Clinic

Full name of responsible person

Dr. Zohreh Tabassi

Street address

Shahid Beheshti Avenue, Kashan

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8115187159

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tabasi_z@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Zohreh Tabassi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available