Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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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+98 31 5546 3378

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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
Isfehan

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 measrement (hours)

2

Description
induction time to delivery time
Timepoint
after the intervention
Method of measurement
time measrement (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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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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hamidi_gh@kaums.ac.ir
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 updating data

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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