Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of vaginal suppository of Fenugreek on cervical ripening and onset of labor in nulliparous women

Protocol summary

Study aim

Determination of the effect of vaginal suppository of fenugreek on cervical ripening and onset of labor in nulliparous women

Design

A clinical trial with a control group, without blinding, randomized and with parallel groups design of 60 mothers with 40 weeks of gestation are allocated into two intervention and control groups using simple randomization online, by the sequence created at www.graphpad.com/quickcalcs;

Settings and conduct

Samples will be selected from the mothers who refer to the midwifery clinic of Umm Al-Banin Hospital in Mashhad. Vaginal examination will be performed by the researcher to determine the Bishop's score.The intervention group will use 0ne 7% vaginal suppository of fenugreek for 3 nights before sleep. Both groups will be advised to go to the clinic 72 hours after the start of the study if they do not have labor pains, to control and determine the Bishop's score. If there isn,t any problem, they will use the vaginal suppository for 3 more nights. If labor pains do not begin at the beginning of week 41, they will be admitted to the maternity ward to terminate the pregnancy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: primiparous women, Gestational age 40 weeks, 18 to 35 years, Singleton pregnancy, Cephalic presentation, Body mass index 18.5 to 30, Intact fetal membranes, Reactive non-stress test Exclusion criteria: Sensitivity to fenugreek, Medical and obstetric problems

Intervention groups

The intervention group will use vaginal suppository of fenugreek daily from the 40 week of gestation for 7 days or until delivery before sleeping. In the control group, routine care is performed.

Main outcome variables

Cervical ripening ;Initiation of labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200426047210N1**
Registration date: **2020-07-26, 1399/05/05**
Registration timing: **prospective**

Last update: **2020-07-26, 1399/05/05**
Update count: **0**

Registration date

2020-07-26, 1399/05/05

Registrant information

Name
Maryam Ghasemi
Name of organization / entity
Country
Iran (Islamic Republic of)
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ghasemim972@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-05, 1399/05/15

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vaginal suppository of Fenugreek on cervical ripening and onset of labor in nulliparous women

Public title
Effect of Fenugreek on initiation of labor
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Nulliparous women 18 to 35 years old Gestational age 40 weeks based on LMP or ultrasound of the first trimester of pregnancy Cephalic presentation Singleton pregnancy Bishop score of 4 or less Intact fetal membranes Reactive non-stress test Body mass index 18.5 to 30
Exclusion criteria:
Sensitivity to fenugreek Medical and obstetric problems
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling is performed at the obstetric clinic of Omolbanin hospital in Convenience Sampling method based on inclusion and exclusion criteria. Research units are allocated into two intervention and control groups using simple randomization online, by the sequence created at www.graphpad.com/quickcalcs;
Blinding (investigator's opinion)
Not 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 Mashhad University of Medical Sciences
Street address
Assistance of Research and Technology of Mashhad University of Medical Sciences, Qurashi building, Daneshgah avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
91388-13944
Approval date
2020-07-14, 1399/04/24
Ethics committee reference number
IR.MUMS.NURSE.REC.1399.031

Health conditions studied

1

Description of health condition studied
cervical ripening and initiation of labor
ICD-10 code
O80.0
ICD-10 code description
Spontaneous vertex delivery

Primary outcomes

1

Description
Cervical ripening
Timepoint
Before intervention,3 days,1 week after intervation and at the time of hospitalization
Method of measurement
Examination

2

Description
Onset of labour
Timepoint
Before intervention,3 days,1 week after intervation and at the time of hospitalization
Method of measurement
Examination

Secondary outcomes

1

Description
Type of delivery
Timepoint
After delivry
Method of measurement
Observation

2

Description
Neonatal Apgar
Timepoint
After delivry
Method of measurement
Observation

Intervention groups

1

Description
Intervention group: The intervention group after determining the bishop score, uses a 7% vaginal suppository of fenugreek every night before sleep from the 40th week of gestation for 7 days or until delivery. If labor does not begin, three days later, they refer to determine the bishop score and non-stress test (NST). If labor does not begin until the 41th week, the mother will be referred to the maternity hospital to terminate the pregnancy.

Category
Other

2

Description
Control group: In the control group, no intervention will be performed after determining the bishop score. Also, after three days, they refer to determine the bishop score and non-stress test (NST). If labor does not begin until the 41th week, the mother will be referred to the maternity hospital to terminate the pregnancy.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Omolbanin hospital

Full name of responsible person
Farideh Akhlaghi

Street address
Omolbanin hospital, Ayatollah Bahjat 16, Ayatollah Bahjat Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

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Assistance of Research and Technology of Mashhad University of Medical Sciences, Qurashi building, Daneshgah avenue

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Maryam Ghasemi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Mashhad College of nursing and midwifery, Ibn Sina Ave., Doctora intersection, Daneshgah Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Samira Ebrahimzadeh Zagami

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Maryam Ghasemi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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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