

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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 One 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)

Phone

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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 intervention and at the time of hospitalization

Method of measurement

Examination

2

Description

Onset of labour

Timepoint

Before intervention, 3 days, 1 week after intervention and at the time of hospitalization

Method of measurement

Examination

Secondary outcomes

1

Description

Type of delivery

Timepoint

After delivery

Method of measurement

Observation

2

Description

Neonatal Apgar

Timepoint

After delivery

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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9137913199

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Email

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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

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Full name of responsible person

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Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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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