

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of rosewater on cervical ripening in nulliparous women

Protocol summary

Study aim

The purpose of this randomized clinical trial study is to determine the effect of rosewater on cervical ripening in nulliparous women.

Design

A clinical trial study, with a control group, randomized allocation of 60 eligible pregnant women.

Settings and conduct

The participants were nulliparous pregnant women referring to Sayed Mostafa Khomeini Hospital, Tabas and eligible for inclusion in the study. The study lasts for 1 week from the gestational age 40 weeks, which is assessed before, three days and seven days after the start of the intervention, the bishop score and the risk symptoms.

Participants/Inclusion and exclusion criteria

The study population included 60 nulliparous women, 18 to 35 years old with a gestational age of 40 weeks, a Bishop score of 4 or less, and a low-risk pregnancy.

Intervention groups

Study in two groups: 1- Rosewater, which for one week after 40 weeks of gestation, daily consumes 5 ml of rose water. 2- Control group (routine care).

Main outcome variables

Cervical ripening

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180904040952N1**
Registration date: **2018-12-12, 1397/09/21**
Registration timing: **prospective**

Last update: **2018-12-12, 1397/09/21**

Update count: **0**

Registration date

2018-12-12, 1397/09/21

Registrant information

Name

Reihaneh Jarrahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of rosewater on cervical ripening in nulliparous women

Public title

The effect of rosewater on cervical ripening

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Residence in Tabas city Age between 18 to 35 years
Nulliparous women with 40 weeks gestational age
Singleton pregnancy with cephalic presentation Bishop score less than or equal 4 Intact amniotic sac Normal pattern of fetal heart rate The natural number of fetal movements or reactive non-stress test Estimated fetal weight between 2500 to 4000

Exclusion criteria:

The presence of medical and obstetric problems in the present pregnancy Patients with previous cesarean section or hysterotomy Placenta previa and history of third trimester hemorrhage Pelvic examination, intercourse and stimulation of the nipple during the last 24 hours or during the study Laxatives, herbal, chemical, or traditional methods to start a labor within the last 24 hours or during the study Irregular consumption or non-use of rose water during one week of study Delivery in a central location other than Tabas Hospital Patient intolerance Regular uterine contractions

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

At first, the samples are selected based on the target, then they will be assigned to the intervention and control groups using the permutation blocks method. This allocation will occur with the use of software and without the involvement of human factors(Random Allocation software).

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**

The Ethics Committee of the Mashhad Medical Science University

Street address

Qureishi building, Daneshgah Ave, Mashhad

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Razavi Khorasan

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Approval date

2018-12-02, 1397/09/11

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.057

Health conditions studied**1****Description of health condition studied**

Cervical ripening

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Cervical ripening measurement

Timepoint

Before the intervention, three days and seven days after the beginning intervention

Method of measurement

Cervical Bishop score

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For 7 days, once a day, the amount of 5 ml of rose water of Kashan (with 24% of the essential oil of Damask rose) drink at a specified hour of the day. The first examination and check of contraction is when entering the study. Then, on the third and seventh day after the intervention, will be performed. Also, three days after the start of the intervention, the NST is done.

Category

N/A

2**Description**

Control group: In the control group, routine care is performed. The first examination and check of contraction is when entering the study. Then, on the third and seventh day after the intervention, will be performed. Also, three days after the start of the intervention, the NST is done.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Seyyed Mostafa Khomeini Hospital

Full name of responsible person

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Reihaneh Jarrahi

Position

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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

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Full name of responsible person

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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