

# 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)

##### Phone

+98 56 3283 1661

##### Email address

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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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**Province**

Razavi Khorasan

**Postal code**

91735-951

**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**

Dr. Elham Esform

**Street address**

Shahid Seyyed Mostafa Khomeini Hospital, Motahari Blvd, Tabas Golshan

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Reihaneh Jarrahi

**Position**

Master of science student of midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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

Mashhad University of Medical Sciences

**Full name of responsible person**

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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**

Mashhad University of Medical Sciences

**Full name of responsible person**

BiBi Sedigheh Shariat Moghani

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Master

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Position**

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**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