

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The Compare of effect of Camellia sinensis (green tea) and the Myrtus communis ointment on the perineal pain and episiotomy wound healing in nulliparous women.

#### Protocol summary

##### Study aim

The Compare of effect of Camellia sinensis (green tea) and the Myrtus communis ointment on the perineal pain and episiotomy wound healing in nulliparous women.

##### Design

Participants randomly pick one card. The researcher does not know which card contains which ointment. Outcome Assessor (midwife) records the outcome of each individual trial without knowing the person participating in the study.

##### Settings and conduct

Prior to the intervention, the exper midwife will train face to face all three groups about how to care of the perineum and sutures, personal hygiene, nutrition, physical activity, and how to use ointment. Research samples are asked to put one finger strap on the suture area after washing and drying the perineal area, to cover it, and then use a sanitary pad after 10 minutes. Continue twice a day, morning and night before bedtime for 14 days after delivery. The first dose of the drug will be administered in the first 24 hours (at least 2 hours after episiotomy repair) by the patient with the supervision of a researcher at the hospital. If you do not relieve the pain of painkillers Research units will be free to use painkillers after completing the VAS questionnaire ( use 250 mg Mefenamic Acid Pain Score Score). episiotomy improvement will be evaluated on days 7, 10, and 14 .so researcher will Call the patient to observe episiotomy improvement in Elahadi and Ganjavian hospital at 6, 9, and 13 days postpartum based on Objective Wound Assessment (REEDA) and VAS Pain Assessment Tool (by the researcher) Check and record. shoushtar alhadi Hospital - Ganjavian Dezful Hospital

##### Participants/Inclusion and exclusion criteria

nulliparous women Singleton live fetus BMI in the range of 19.8-29.9 Baby weight between 2500-4000 gr

##### Intervention groups

Green Tea Ointment Myrtus communis ointment

##### Main outcome variables

perineal pain and episiotomy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190804044428N1**

Registration date: **2019-10-04, 1398/07/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-10-04, 1398/07/12**

Update count: **0**

##### Registration date

2019-10-04, 1398/07/12

##### Registrant information

##### Name

Azam Jahngirimehr

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3622 8926

##### Email address

jahangirimehr-a@shoushtarums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2020-03-20, 1399/01/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Compare of effect of Camellia sinensis (green tea) and the Myrtus communis ointment on the perineal pain and episiotomy wound healing in nulliparous women.

**Public title**

The Compare of effect of Camellia sinensis (green tea) and the Myrtus communis ointment on the perineal pain and episiotomy wound healing

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

nulliparous women Singleton live fetus BMI in the range of 19.8-29.9 Baby weight between 2500-4000 gr

**Exclusion criteria:**

using the drugs that prevent the maternal wound healing diseases affecting wound healing

**Age**

From **18 years** old to **35 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples are sorted by random allocation. Cards will be prepared in three colors (for the three study groups) and placed in a bag and the samples will be asked to randomly pick one of the cards. The color of the card will determine the type of ointment tube. The color of the card and the tube will be recorded in the research sample questionnaire.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants randomly pick a card and a researcher unaware of what color of lipstick which each person has his own record cards. Outcome Assessor (midwife) records the outcome of each individual trial without knowing the person participating in the study.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Shoushtar faculty of Medical sciences

**Street address**

Shahid Rajae West intersection, Shoushtar faculty of Medical sciences

**City**

SHoushtar

**Province**

Khouzestan

**Postal code**

6451684534

**Approval date**

2019-07-10, 1398/04/19

**Ethics committee reference number**

IR.SHOUSHTAR.REC.1398.004

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

perineal pain and episiotomy

**ICD-10 code**

085-092

**ICD-10 code description**

Chapter XV: Pregnancy, childbirth and the puerperium

**Primary outcomes****1****Description**

Pain level

**Timepoint**

7, 10 and 14 postpartum

**Method of measurement**

VAS index

**Secondary outcomes**

empty

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

Intervention group: Green Tea Ointment

**Category**

Treatment - Other

## 2

### Description

Intervention group: Myrtus communis ointment

### Category

Treatment - Other

## 3

### Description

Control group: Placebo

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

AL-Hadi Hospital

##### Full name of responsible person

Masoumeh Saiahi

##### Street address

Shahid Rajai intersection

##### City

shoushtar

##### Province

Khouzestan

##### Postal code

6451684534

##### Phone

+98 61 3621 0399

##### Email

research@shoushtarums.ac.ir

## 2

#### Recruitment center

##### Name of recruitment center

Ganjavian Hospital

##### Full name of responsible person

Masoumeh Saiahi

##### Street address

At the beginning of Andimeshk Road - in front of the  
292th Armored Brigade

##### City

dezfool

##### Province

Khouzestan

##### Postal code

6461665145

##### Phone

+98 61 4242 2040

##### Email

bbd@dums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Faculty of Medical Sciences of shoushtar

##### Full name of responsible person

Sayahi Masoumeh

##### Street address

Faculty of Medical Sciences of shoushtar, Alhadi  
Hospital, Shahid Rajaei intersection

##### City

shoushtar

##### Province

Khouzestan

##### Postal code

6451684534

##### Phone

+98 61 3622 8927

##### Email

research@shoushtarums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Faculty of Medical Sciences of shoushtar

##### 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

Faculty of Medical Sciences of shoushtar,

##### Full name of responsible person

Saiahi Masoumeh

##### Position

lecturer

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

##### Street address

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##### Province

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##### Postal code

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##### Phone

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m.saiahi430@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

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**Name of organization / entity**

Faculty of Medical Sciences of Shoushtar

**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Because of the confidentiality of each person's study results

**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**

Not applicable