

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Effect of green tea ointment versus placebo on episiotomy pain and wound healing in women who delivered: a double-blind randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of green tea ointment versus placebo on episiotomy pain and wound healing in women who delivered

##### Design

This is a double-blind randomized clinical trial, phase II, in which 130 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible women who delivered and will refer to Fatemeh Hospital during the study period will be enrolled in the trial

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 35 years; Gestational age of 35 weeks or higher; Medio lateral incision and 2nd degree episiotomy; Normal body mass index Exclusion criteria: Cigarette smoking; Condiloma lesions or herpes in perinea; Preeclampsia Diabetes Coagulopathy Cardiovascular diseases Respiratory disease Renal failure

##### Intervention groups

Intervention group: Green tea ointment twice on location of episiotomy wound for 10 days Control group: Placebo ointment twice on location of episiotomy wound for 10 days

##### Main outcome variables

Primary outcome: Episiotomy wound healing Episiotomy wound pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N228**

Registration date: **2018-08-02, 1397/05/11**

Registration timing: **prospective**

Last update: **2018-08-02, 1397/05/11**

Update count: **0**

##### Registration date

2018-08-02, 1397/05/11

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-09-23, 1398/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of green tea ointment versus placebo on episiotomy pain and wound healing in women who delivered: a double-blind randomized clinical trial

##### Public title

Effect of green tea ointment versus placebo on

episiotomy pain and wound healing in women who delivered

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age of 18 to 35 years; Gestational age of 35 weeks or higher; Medio lateral incision and 2nd degree episiotomy; Normal body mass index

#### Exclusion criteria:

Cigarette smoking; Condiloma lesions or herpes in perineal; Preeclampsia Diabetes Coagulopathy Cardiovascular diseases Respiratory disease Renal failure

### Age

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

### Gender

Female

### Phase

2

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

### Sample size

Target sample size: **130**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

### City

Hamadan

### Province

Hamadan

### Postal code

6517838695

### Approval date

2018-07-21, 1397/04/30

### Ethics committee reference number

IR.UMSHA.REC.1397.324

## Health conditions studied

### 1

#### Description of health condition studied

Episiotomy

#### ICD-10 code

O90.1

#### ICD-10 code description

Disruption of perineal obstetric wound

## Primary outcomes

### 1

#### Description

Episiotomy wound healing

#### Timepoint

5 and 10 days after intervention

#### Method of measurement

With physical examination

### 2

#### Description

Episiotomy wound pain

#### Timepoint

6 hours after intervention

#### Method of measurement

Using visual analog scale (VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Green tea ointment twice on location of episiotomy wound for 10 days

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo ointment twice on location of episiotomy wound for 10 days

#### Category

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Fatemieh Hospital

**Full name of responsible person**

Dr Farideh Kazemi

**Street address**

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

faridehkazemi21@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

info.research@umsha.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Farideh Kazemi

**Position**

PhD in Midwifery

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

faridehkazemi21@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Seyyedeh Zahra Masoomi

**Position**

Fertility Health Specialist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

Zahramid2001@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Email**

poorolajal@umsha.ac.ir

**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