

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