

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of the effect of a combination cream of olive and honey versus routine care on episiotomy wound healing and its pain severity in primiparous women: a randomized clinical trial

Protocol summary

Study aim

To compare the effect of combination cream of olive and honey versus routine care on episiotomy wound healing and its pain severity in primiparous women

Design

This a randomized clinical trial, phase II, in which 80 eligible primiparous women will be randomly assigned to the intervention and control groups

Settings and conduct

The primiparous women with episiotomy who will refer to fatemieh Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of 18 to 40 years; term pregnancy; primiparous; normal delivery with episiotomy; normal body mass index. Exclusion criteria: chronic disease; symptomatic vaginal infection; allergic diseases; rapture with grade of 3 or 4; puerperium fever.

Intervention groups

Intervention group: routine treatment plus topical use of a combination cream of olive and honey twice daily for 10 days. Control group: just routine treatment.

Main outcome variables

Primary outcome: wound healing on 1, 7, 10, and 14 days after intervention through physical examination; severity of episiotomy pain on 1, 7, 10, and 14 days after intervention with using Mc Gill ruler.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N208**

Registration date: **2018-03-04, 1396/12/13**

Registration timing: **prospective**

Last update: **2018-03-04, 1396/12/13**

Update count: **0**

Registration date

2018-03-04, 1396/12/13

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-11, 1396/12/20

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of a combination cream of olive and honey versus routine care on episiotomy wound healing and its pain severity in primiparous women: a randomized clinical trial

Public title

Comparison of the effect of a combination cream of olive and honey versus routine care on episiotomy wound healing and its pain severity in primiparous women

IR.UMSHA.REC.1396.823

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 40 years Term pregnancy Primiparous Normal delivery with episiotomy Normal body mass index

Exclusion criteria:

Chronic disease Symptomatic vaginal infection Allergic diseases Rapture with grade of 3 or 4 Puerperium fever

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

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)

Not blinded

Blinding description

Placebo

Not 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

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Postal code

6517838695

Approval date

2018-02-24, 1396/12/05

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Episiotomy wound

ICD-10 code

O86.0

ICD-10 code description

Infection of obstetric surgical wound

Primary outcomes

1

Description

Wound healing

Timepoint

On 1, 7, 10, and 14 days after intervention

Method of measurement

Through physical examination

2

Description

Severity of episiotomy pain

Timepoint

On 1, 7, 10, and 14 days after intervention

Method of measurement

Using Mcgill ruler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus topical use of a combination cream of olive and honey twice daily for 10 days

Category

Treatment - Drugs

2

Description

Control group: Just routine treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Arezoo Shayan

Street address

Fatemieh Hospital, Pasdaran Ave.

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

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

Arezoo Shayan

Position

Master of Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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

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Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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