Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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

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

IR.UMSHA.REC.1396.823

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
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Sponsors / Funding sources

1

Sponsor
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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

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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