Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Honey Ointment on the Pain Severity and Healing of Women Genital Herpes Lesions.

Protocol summary

Study aim
Comparison of pain severity in two groups of intervention and control before, 7 and 10 days after treatment. Comparison of lesions healing in two groups of two groups of intervention and control before, 7 and 10 days after treatment.

Design
A randomized controlled clinical trial with parallel groups, Triple-blind, four-block randomized block

Settings and conduct
The Research Environment is the dermatology clinic of Razi Hospital and Imam Khomeini Hospital. 68 of women who referred to this center and their wounds were diagnosed herpes by a doctor, will be divided into two groups using 4-block randomized method. The severity of pain and stage of lesion will be recorded and repeated on days 0, 7 and 10. How to get blind is that the researcher, the participents , and the statistics consultant are unaware of the type of drug being administered, and both drugs are provided in identical formats and with specific codes by the pharmacist.

Participants/Inclusion and exclusion criteria
Initial Herpes Genital Needs treatment for active Wounds Non-use of effective medications for Wound Healing (Anticoagulants, Anti-depressant, Alcohol, Glucocorticoids, immunosuppressive drugs, Chemotherapy, drugs, Psychotropic drugs) Lack of disease that disrupts Wound Healing (Chronic systemic diseases, Heart disease, kidney disease, Lung disease, Coagulopathy, Immune deficiency,Connective tissue disorder, Diabetes, Anemia, mental illnesses, hemophilia, Depression, Malnutrition) Lack of Pregnancy or Lactation

Intervention groups
Intervention group: Oral Aciclovir 400 mg 3 times daily with honey ointment 5 times daily. Control group:Oral Aciclovir 400 mg 3 times daily with placebo ointment 5 times daily.

Main outcome variables
Severity of pain Healing of lesions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160821029446N6**
Registration date: **2020-03-24, 1399/01/05**
Registration timing: **prospective**

Last update: **2020-03-24, 1399/01/05**
Update count: **0**

Registration date
2020-03-24, 1399/01/05

Registrant information

Name
Maryam Damghanian

Name of organization / entity
Nursing and Midwifery Faculty, Tehran University of Medical Science

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-20, 1399/02/31

Expected recruitment end date
2020-12-20, 1399/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Honey Ointment on the Pain Severity and Healing of Women Genital Herpes Lesions.

Public title
The Effect of Honey Ointment on the Pain Severity and Healing of Women Genital Herpes Lesions.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Initial Herpes Genital Needs treatment for active Wounds Non-use of effective medications for Wound Healing (Anticoagulants, Anti-depressant, Alcohol, Glucocorticoids, immunosuppressive drugs, Chemotherapy, drugs, Psychotropic drugs) Lack of disease that disrupts Wound Healing (Chronic systemic diseases, Heart disease, kidney disease, Lung disease, Coagulopathy, Immune deficiency,Connective tissue disorder, Diabetes, Anemia, mental illnesses, hemophilia, Depression, Malnutrition) Lack of Pregnancy or Lactation

Exclusion criteria:

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will be randomly divided into two groups of intervention and control, so that we first design 4 blocks of different types of probability, so that in each block two of the intervention group and two of the control group will be placed. The number of possibilities in this case will be 6. Then create a list of random numbers between 1 and 6 and arrange the blocks according to the list of numbers obtained until the total number of samples is covered. Accordingly, individuals are divided into two groups. The intervention group will be the group that will take oral acyclovir with honey ointment and the control group will be the group that will take oral acyclovir with placebo.

Blinding (investigator's opinion)
Triple blinded

Blinding description
This Study will be a Randomized Controlled Trial, Triple-blind, Placebo-Controlled Clinical Trial. The Drugs are already divided by the Pharmacist. How to get Blind is that the Participants, the Researcher, and the Statistics Consultant are Unaware of the Type of Drug being Administered, and both Drugs are provided in identical formats and with specific codes by the Pharmacist and are provided to research units. Participants and Researcher will not be aware of the Drug codes, only the Pharmacist will determine the Drug code, and will be decrypted after the Data is collected and completed. The dose of Acyclovir in both groups will be the same as prescribed.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Nursing and Midwifery and Rehabilitation Faculty of Tehran University of Medical

Street address
Nursing and Midwifery Faculty of Tehran University of Medical Sciences, Tohid Square, Tehran

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Tehran

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1419733171

Approval date
2020-02-12, 1398/11/23

Ethics committee reference number
IR.TUMS.FNM.REC.1398.172

Health conditions studied

1

Description of health condition studied
genital herpes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Severity of Pain

Timepoint
At the beginning of the study and 7 and 10 days after intervention

Method of measurement
VAS tool

2

Description
Healing of lesions
Timepoint
At the beginning of the study and 7 and 10 days after intervention
Method of measurement
Observation and Ruler

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group will take oral aciclovir 400 mg 3 times daily for 7-10 days or until clinical symptoms resolve, with honey ointment 5 times daily until the skin returns to normal or up to 10 Day (whichever happened earlier). Initial clinical evaluation will be done at the time of enrollment (day zero) and severity of pain and lesion will be recorded and repeated on days 7 and 10.
Category
Treatment - Drugs

2

Description
Control group: This group will take oral aciclovir 400 mg 3 times daily for 7-10 days or until clinical symptoms resolve, with Placebo ointment 5 times daily until the skin returns to normal or up to 10 Day (whichever happened earlier). Initial clinical evaluation will be done at the time of enrollment (day zero) and severity of pain and lesion will be recorded and repeated on days 7 and 10.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeyni Hospital
Full name of responsible person
Maryam Damghanian
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Recruitment center
Name of recruitment center
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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
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shahnoush Gerami

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

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Position

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Latest degree

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Other areas of specialty/work

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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

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available