

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 participants, 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

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

m-damghanian@sina.tums.ac.ir

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

City

Tehran

Province

Tehran

Postal code

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

Street address

School of Nursing & Midwifery, East Nosrat Ave, Towhid Square.Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4222

Email

maryam_damghanian@yahoo.com

2

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Maryam Damghanian

Street address

Razi Dermatology Specialty Hospital, Razi Dead End, Vahdat-e-Eslami Square, Vahdat-e-Eslami St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5563 0174

Fax

+98 21 5562 0300

Email

maryam_damghanian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Esmat Karimi

Street address

No23, Dameshgh street, Valiasr street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4222

Email

maryam_damghanian@yahoo.com

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

Midwifery

Street address

School of Nursing & Midwifery, Tehran University of
Medical sciences, Tohid Sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Email

sh.gerami1990@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Damghanian

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

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

City

Tehran

Province

Tehran

Postal code

1419733172

Phone

+98 21 6692 7171

Fax

Email

Maryam_damghanian@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Damghanian

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

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

City

Tehran

Province

Tehran

Postal code

1419733172

Phone

+98 21 6692 7171

Fax

Email

Maryam_damghanian@yahoo.com

Web page address

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