# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 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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**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**
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**Full name of responsible person**
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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

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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