

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Investigation Of The Effect Of Herbix compound In The Treatment Of Facial Herpes.

#### Protocol summary

##### Study aim

.Determining the effect of Herbix combination in the treatment of facial herpes

##### Design

A clinical trial with a control group, with parallel groups, single-blind, randomized, phase 2 for 10 patients.

##### Settings and conduct

.Patients are introduced to Targaba health network and. Before starting the treatment, a blood sample and wound tissue sample, real time PCR and a photo of the wound will be taken. One drop of Herbix medicine will be used on the wound. Follow-up will be done for one month. Demographic and clinical information will be collected from the case, test and observation. After one month, the blood test will be repeated and a photo will be taken of the place where the herpes has healed. In this study, we will investigate the variables of HDF, 8-OH-dG, HSV-1 gene, caspase-3 gene, caspase-9 gene, and Anti-Herpes cytotoxicity.

##### Participants/Inclusion and exclusion criteria

Clinical Lyme Herpes such as tingling and itching around the wound Small blisters filled with liquid on the skin of the face Scaling of small merged blisters Fluid secretion

##### Intervention groups

5 control group patients have facial herpes sores will receive only the selected drug Acyclovir (the same drug as the doctor's opinion) and for the intervention group, 5 patients will receive the drug Acyclovir in addition to Herbix.

##### Main outcome variables

.Herbix, HDF fibroblast cell, 8-OH-dG, HSV-1 gene, caspase-3 gene, caspase-9 gene, Anti-Herpes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231030059908N2**

Registration date: **2023-12-25, 1402/10/04**

Registration timing: **prospective**

Last update: **2023-12-25, 1402/10/04**

Update count: **0**

##### Registration date

2023-12-25, 1402/10/04

##### Registrant information

###### Name

Fateme Mollazade

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 5523 4944

###### Email address

f.mollazade1159@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-21, 1402/11/01

##### Expected recruitment end date

2024-09-21, 1403/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigation Of The Effect Of Herbix compound In The Treatment Of Facial Herpes.

##### Public title

Herbix compound In The Facial Herpes.

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Clinical symptoms of herpes such as tingling and itching around the wound. Small blisters filled with liquid on the skin of the face. Scaling of small merged blisters. Fluid secretion.

**Exclusion criteria:**

**Age**  
No age limit

**Gender**  
Both

**Phase**  
1-2

**Groups that have been masked**

- Care provider

**Sample size**  
Target sample size: 15

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
.In this study, the clinical caregivers of this doctor and her assistants.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**  
Ethics Committee in Biomedical Research, Mashhad Unit

**Street address**  
Mashhad, 14 Imam Khomeini Street, Faculty of Medicine, Azad University

**City**  
Mashhad

**Province**  
Razavi Khorasan

**Postal code**  
9187147578

**Approval date**  
2023-11-19, 1402/08/28

**Ethics committee reference number**  
IR.IAU.MSHD.REC.1402.135

## Health conditions studied

### 1

**Description of health condition studied**  
herpes simplex

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**  
RNA extraction

**Timepoint**  
At the beginning of the study, on the thirtieth day.

**Method of measurement**  
HDF fibroblast cell, 8-OH-dG, HSV-1 gene, caspase-3 gene, caspase-9 gene, Anti-Herpe

### 2

**Description**  
Real-time Polymerase chain reaction investigation

**Timepoint**  
At the beginning of the study, on the thirtieth day

**Method of measurement**  
Commercial kit of Ben Yakhte company

### 3

**Description**  
Antiviral antibody level in serum

**Timepoint**  
At the beginning of the study, on the thirtieth day

**Method of measurement**  
ELISA technique and abCAM company kit

### 4

**Description**  
DNA damage

**Timepoint**  
The beginning of the study

**Method of measurement**  
8-OH-dG level in culture supernatant

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**  
Intervention group: In addition to the standard treatment for Herpes Simplex, this group receives a new drug called Herbix

**Category**  
Treatment - Drugs

## 2

### Description

Control group: They receive only the standard drug, acyclovir

### Category

Treatment - Drugs

## 3

### Description

Intervention group: Intervention group: After confirming the effect of Herbex drug, this time patients will only receive Herbix drug.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Reza hospital

#### Full name of responsible person

Gholamreza Karamatian

#### Street address

Ebn Sina Street, Imam Reza Square, Imam Reza Hospital, Mashhad Town.

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

1708534

#### Phone

+98 51 3854 3031

#### Email

info@scanteb.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Gholamreza Keramatiyan

#### Street address

48, Abdulmutallab, Shahid Qorani Blvd. Mashhad Town

#### City

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#### Province

Razavi Khorasan

#### Postal code

9196664944

#### Phone

+98 51 3607 1468

#### Email

keramatiyanGH1@gmail.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Islamic Azad University

### Proportion provided by this source

100

### Public or private sector

Private

### 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

Islamic Azad University

#### Full name of responsible person

Gholamreza Keramatiyan

#### Position

Non-faculty general practitioner

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Family Physician

#### Street address

48, Abdulmutallab, Shahid Qorani Blvd, Mashhad Town

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#### Postal code

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#### Phone

0098513529717

#### Email

keramatiyanGH1@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Mohamadreza KHakzad

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Immunology

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Rezashahr, No. 83, Daabel Khazai 2, Mashhad Town

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f.mollazade1159@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Fateme Mollazade  
**Position**  
Student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Others  
**Street address**  
No.8/Alaleh Ave/ Pirouzi Blvd/ Mashhad Town  
**City**  
Mashhad  
**Province**  
Razavi Khorasan

## 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