

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Evaluation of the treatment of cutaneous leishmaniasis with Epigallocatechin Gallate, as topical supplemental therapy (A RCT study)

#### Protocol summary

##### Study aim

Evaluation of cutaneous leishmaniasis treatment with Epigallocatechin Gallate compared with the standard group.

##### Design

Intervention Group 1: Includes ten people with USP hydrophilic ointment (EGCG) (2%) in one of the wounds plus glucantime to increase the effectiveness compared to the other wound of the patient who is treated only with glucantime. Intervention Group 2: Includes ten people with USP hydrophilic ointment (EGCG) (5%) in one of the wounds plus glucantime to increase the effectiveness compared to the other wound of the patient who is treated only with glucantime.

##### Settings and conduct

Haft Tir BLV - Villa Street

##### Participants/Inclusion and exclusion criteria

There are at least two lesions, in one case intervention + glucantime and in the other lesion only glucantime is prescribed. 15 to 60 years Skin lesions at least one centimeter in size Leishmaniasis confirmed by a parasitologist consent signature

##### Intervention groups

Intervention Group 1: Includes ten people with USP hydrophilic ointment (EGCG) (2%) in one of the wounds plus glucantime to increase the effectiveness compared to the other wound of the patient who is treated only with glucantime. Intervention Group 2: Includes ten people with USP hydrophilic ointment (EGCG) (5%) in one of the wounds plus glucantime to increase the effectiveness compared to the other wound of the patient who is treated only with glucantime.

##### Main outcome variables

Twice a week, the lesions is examined by a dermatologist with some index of wound healing. Every three days to 45 days, the final assessment is performed by the research team.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180526039848N2**

Registration date: **2021-04-27, 1400/02/07**

Registration timing: **retrospective**

Last update: **2021-04-27, 1400/02/07**

Update count: **0**

##### Registration date

2021-04-27, 1400/02/07

##### Registrant information

##### Name

Elham Moghaddase

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3884 9410

##### Email address

moghaddase@mums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2020-12-20, 1399/09/30

##### Expected recruitment end date

2021-03-09, 1399/12/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

|                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                                                                                                                                                                                                      |
|-------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Evaluation of the treatment of cutaneous leishmaniasis with Epigallocatechin Gallate, as topical supplemental therapy (A RCT study) |                                                                                                                                                                                                                                                                                                                                                                                                              | Ethics Committee of Mashhad University of Medical Sciences |                                                                                                                                                                                                                                      |
| <b>Public title</b>                                                                                                                 | Evaluation of the treatment of cutaneous leishmaniasis with Epigallocatechin Gallate                                                                                                                                                                                                                                                                                                                         | <b>Street address</b>                                      | Azadi square-medical university                                                                                                                                                                                                      |
| <b>Purpose</b>                                                                                                                      | Treatment                                                                                                                                                                                                                                                                                                                                                                                                    | <b>City</b>                                                | Mashhad                                                                                                                                                                                                                              |
| <b>Inclusion/Exclusion criteria</b>                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Province</b>                                            | Razavi Khorasan                                                                                                                                                                                                                      |
| <b>Inclusion criteria:</b>                                                                                                          | There are at least two lesions, in one case intervention + glucantime and in the other lesion only glucantime is prescribed. 15 to 60 years Skin lesions at least one centimeter in size Leishmaniasis confirmed by a parasitologist consent signature                                                                                                                                                       | <b>Postal code</b>                                         | 13131 - 99137                                                                                                                                                                                                                        |
| <b>Exclusion criteria:</b>                                                                                                          | People who do not use the drug according to the plan<br>People who do not go to the clinic on the scheduled days                                                                                                                                                                                                                                                                                             | <b>Approval date</b>                                       | 2021-04-10, 1400/01/21                                                                                                                                                                                                               |
| <b>Age</b>                                                                                                                          | From <b>15 years</b> old to <b>60 years</b> old                                                                                                                                                                                                                                                                                                                                                              | <b>Ethics committee reference number</b>                   | IR.MUMS.MEDICAL.REC.1400.009                                                                                                                                                                                                         |
| <b>Gender</b>                                                                                                                       | Both                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Health conditions studied</b>                           |                                                                                                                                                                                                                                      |
| <b>Phase</b>                                                                                                                        | 2-3                                                                                                                                                                                                                                                                                                                                                                                                          | <b>1</b>                                                   |                                                                                                                                                                                                                                      |
| <b>Groups that have been masked</b>                                                                                                 | <ul style="list-style-type: none"> <li>Participant</li> <li>Outcome assessor</li> <li>Data analyser</li> </ul>                                                                                                                                                                                                                                                                                               | <b>Description of health condition studied</b>             | cutaneous leishmaniasis                                                                                                                                                                                                              |
| <b>Sample size</b>                                                                                                                  | Target sample size: <b>40</b>                                                                                                                                                                                                                                                                                                                                                                                | <b>ICD-10 code</b>                                         | B55.1                                                                                                                                                                                                                                |
| <b>Randomization (investigator's opinion)</b>                                                                                       | Not randomized                                                                                                                                                                                                                                                                                                                                                                                               | <b>ICD-10 code description</b>                             | Cutaneous leishmaniasis                                                                                                                                                                                                              |
| <b>Randomization description</b>                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Primary outcomes</b>                                    |                                                                                                                                                                                                                                      |
| <b>Blinding (investigator's opinion)</b>                                                                                            | Double blinded                                                                                                                                                                                                                                                                                                                                                                                               | <b>1</b>                                                   |                                                                                                                                                                                                                                      |
| <b>Blinding description</b>                                                                                                         | Those who evaluate the outcome are different from those who give the drug to the patient (the doctor gives the medicine) and the consequences will only be written by the code on a separate sheet (the consequences by the code introduced by the student). The statistician does not know any of the groups and does not know the type of treatment and will only do statistical work with specific codes. | <b>Description</b>                                         | lesion size (diameter)                                                                                                                                                                                                               |
| <b>Placebo</b>                                                                                                                      | Not used                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Timepoint</b>                                           | Day of 7, 14, 21, 28, 35, 42                                                                                                                                                                                                         |
| <b>Assignment</b>                                                                                                                   | Parallel                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Method of measurement</b>                               | Image J software                                                                                                                                                                                                                     |
| <b>Other design features</b>                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Secondary outcomes</b>                                  | empty                                                                                                                                                                                                                                |
| <b>Secondary Ids</b>                                                                                                                | empty                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Intervention groups</b>                                 |                                                                                                                                                                                                                                      |
| <b>Ethics committees</b>                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                              | <b>1</b>                                                   |                                                                                                                                                                                                                                      |
| <b>1</b>                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Description</b>                                         | Intervention group: Includes ten people with EGCGin USP hydrophilic ointment (2%) in one of the wounds plus glucantime to increase the effectiveness compared to the other wound of the patient who is treated only with glucantime. |
| <b>Ethics committee</b>                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Category</b>                                            | Treatment - Drugs                                                                                                                                                                                                                    |
| <b>Name of ethics committee</b>                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                              | <b>2</b>                                                   |                                                                                                                                                                                                                                      |
|                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Description</b>                                         | Intervention group: Includes ten people with EGCGin USP hydrophilic ointment (5%) in one of the wounds plus glucantime to increase the effectiveness compared to the other wound of the patient who is treated only with glucantime. |

**Category**  
Treatment - Drugs

**Type of organization providing the funding**  
Academic

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Haft Tir BLV - Villa Street  
**Full name of responsible person**  
Elham Moghaddas  
**Street address**  
Haft Tir BLV - Villa Street  
**City**  
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Razavi Khorasan  
**Postal code**  
9179793945  
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**Email**  
moghaddase@mums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Elham Moghaddas  
**Street address**  
Mashhad.Medical faculty. Parasitology department  
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**Province**  
Razavi Khorasan  
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9177948564  
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**Email**  
moghaddase@mums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Mashhad 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

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Elham Moghaddase  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Parasitology  
**Street address**  
medical faculty  
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**Phone**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Elham Moghaddas  
**Position**  
associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Parasitology  
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moghaddase@mums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences

**Full name of responsible person**

Elham Moghaddas

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Parasitology

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**Province**

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9177948564

**Phone**

+98 51 3800 2406

**Email**

moghaddase@mums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

All images of patients' wounds during treatment

**When the data will become available and for how long**

Up to 1 year after the completion of the project

**To whom data/document is available**

Project collaborators

**Under which criteria data/document could be used**

Have a face-to-face conversation with project executives  
about your idea

**From where data/document is obtainable**

Have a written request or in person with the project  
executors

**What processes are involved for a request to access data/document**

A written request should be given to the executors of the  
project

**Comments**