

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### Investigating the effectiveness of oral Cicaglucal on wound healing and pruritus management in patients with Epidermolysis bullosa

#### Protocol summary

##### Study aim

Determination of the effectiveness of oral Cicaglucal on wound healing and pruritus management in Epidermolysis bullosa

##### Design

The single-arm clinical trial is without a control group and randomization. The result of the treatment is evaluated by a doctor independent of the study. Patients are evaluated at the beginning of the study and at the end of the fourth week.

##### Settings and conduct

Patients who meet the criteria for inclusion in the study are selected from patients with epidermolysis bullosa who are referred to the Molecular Dermatology Research Center and Shahid Faghihi Dermatology Clinic. The medicine is delivered to the patient in packs of 10 capsules.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with epidermolysis bullosa who have been confirmed by a dermatologist 2. Consent of the patient and the patient's parents to participate in the study 3. The patient complains of skin sores and itching. Exclusion criteria: 1. Positive history of drug hypersensitivity 2. Patients who have problems with swallowing any type of medication

##### Intervention groups

Cicaglucal capsule is administered once a day for up to one month. In cases where patients are unable to take the medicine due to difficulty in swallowing the capsule, the capsule is opened and the contents of the capsule (powder) are given to the patient orally with water.

##### Main outcome variables

The rate of wound and itching in patients with epidermolysis bullosa

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20150825023753N22**

Registration date: **2024-01-09, 1402/10/19**

Registration timing: **prospective**

Last update: **2024-01-09, 1402/10/19**

Update count: **0**

##### Registration date

2024-01-09, 1402/10/19

#### Registrant information

##### Name

Mohammad Mahdi Parvizi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3212 5592

##### Email address

parvizim@sums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2024-01-15, 1402/10/25

#### Expected recruitment end date

2024-06-20, 1403/03/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Investigating the effectiveness of oral Cicaglucal on wound healing and pruritus management in patients with Epidermolysis bullosa

## Public title

The effectiveness of oral Cicaglucal on wound healing and pruritus management in patients with Epidermolysis bullosa

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with epidermolysis bullosa who have been confirmed by a dermatologist Consent of the patient and the patient's parents to participate in the study The patient complains of skin sores and itching

### Exclusion criteria:

Positive history of drug hypersensitivity Patients who have problems with swallowing any type of medication

## Age

From 5 years old

## Gender

Both

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: 15

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Medical School of Shiraz  
University of Medical Sciences

##### Street address

Medical School of Shiraz University of Medical  
Sciences

##### City

Shiraz

##### Province

Fars

##### Postal code

7134845794

#### Approval date

2023-12-20, 1402/09/29

#### Ethics committee reference number

IR.SUMS.MED.REC.1402.430

## Health conditions studied

### 1

#### Description of health condition studied

Epidermolysis bullosa

#### ICD-10 code

Q81

#### ICD-10 code description

Epidermolysis bullosa

## Primary outcomes

### 1

#### Description

The number of wounds on the surface of the patient's body

#### Timepoint

Before drug administration and one month after drug administration

#### Method of measurement

Count the number of wounds

### 2

#### Description

Severity of itching

#### Timepoint

Before drug administration and one month after drug administration

#### Method of measurement

Dynamic Pruritus Score (DPS)

## Secondary outcomes

### 1

#### Description

Overall improvement rate from the patient's point of view

#### Timepoint

One month after taking the drug

#### Method of measurement

Patient global impression of improvement(PGI-I)

### 2

#### Description

Overall improvement rate from the physician's point of view

#### Timepoint

One month after taking the drug

#### Method of measurement

Impression of improvement (CGI-I)

## Intervention groups

### 1

#### Description

Intervention group: Cicaglucal capsule is administered

once a day for up to one month. In cases where patients are unable to take the medicine due to difficulty in swallowing the capsule, the capsule is opened and the contents of the capsule (powder) are given to the patient orally with water.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Faghihi Dermatology Clinic

**Full name of responsible person**

Dr. Nasrin Saki

**Street address**

Shahid Faghihi Hospital, Zand Avenue

**City**

Shiraz

**Province**

Fars

**Postal code**

71348466114

**Phone**

+98 71 3212 5592

**Email**

nasrinsa85@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Hashem Hashempur

**Street address**

Shiraz University of medical Sciences, Research vice,  
Zand Street

**City**

Shiraz

**Province**

Fars

**Postal code**

7134814336

**Phone**

+98 71 3235 7252

**Email**

Hashempur@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Mahdi Parvizi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Zand Ave, Shahid Faghihi Hospital,

**City**

Shiraz

**Province**

Fars

**Postal code**

7134846114

**Phone**

+98 71 3212 5592

**Email**

mmparvizi@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

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## 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

Demographic data and the result of the clinical trial

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

One year later

**To whom data/document is available**

Researchers

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

After the publication of the article based on the clinical trial, it will be possible to share the data. The recipients of the data can use the data by obtaining permission from the project managers. The managers of this project will allow the data to be used in secondary data analysis studies and systematic reviews.

**From where data/document is obtainable**

Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.

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

Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.

**Comments**

Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.