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
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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
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71348466114
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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
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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Email
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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.