Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of the efficacy of topical Gabapentin for the treatment of pruritus in patients with Epidermolysis bullosa, Faghihi hospital, 2021

Protocol summary

Study aim
Evaluation of the efficacy of 10% gabapentin cream compared to base cream without Gabapentin in the treatment of pruritic lesions in patients with Epidermolysis bullosa.

Design
A non-randomized, double-blind; placebo-controlled clinical trial with blinded outcome assessment, 19 patients; convenient sampling.

Settings and conduct
A total of 19 patients with various forms of epidermolysis bullosa referred to the Faghihi Hospital will be included(Available/ convenient Sampling). The dermatologist first identifies two pruritic areas in each patient (A and B), each less than 3% of BSA, and then measures the size and erythema of each area. The lesions will be photographed and the Leuven-Itch-scale questionnaire is completed by the patients. Patients will receive 10% gabapentin cream on one side and base cream on the other (patients and dermatologists are unaware of the type of treatment on each side). Two similar containers are designed with labels A or B, and patients apply them 3 times a day for 6 weeks. Patients then return to the dermatology clinic at the end of week 6, and the rate of erythema, area size, and leuven-Itch-scale and imaging on each side are performed by a dermatologist.

Participants/Inclusion and exclusion criteria
Patients older than 6 years; different forms of epidermolysis bullosa (histologically confirmed); unresponsive to conventional antipruritic treatment, no pregnancy or lactating; no underlying systemic disease or disorders that can make them prone to itching, regardless of skin disease

Intervention groups
Two pruritic lesions are identified in each patient, then one of the lesions is treated with Gabapentin 10% cream (Prepared and formulated in the Dr. Rastegar pharmacy in Shiraz) and another lesion with a gabapentin-free base cream three times a day for 6 weeks.

Main outcome variables
Erythema, lesion size and leuven-itch-scale

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210822052258N1**
Registration date: **2021-09-15, 1400/06/24**
Registration timing: **prospective**

Last update: **2021-09-15, 1400/06/24**
Update count: **0**
Registration date
2021-09-15, 1400/06/24

Registrant information
Name
Samira Vahedi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-09-23, 1400/07/01
Expected recruitment end date
2021-11-22, 1400/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of topical Gabapentin for the treatment of pruritus in patients with Epidermolysis bullosa, Faghihi hospital, 2021

Public title
Evaluation of the efficacy of topical Gabapentin for the treatment of pruritus in patients with Epidermolysis bullosa

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age equal or more than 6 years; Histologically confirmed any three major forms of epidermolysis bullosa (EB simplex (EBS), junctional EB (JEB), and dystrophic EB (DEB)) complain of persistent pruritic lesions unresponsive to the standard treatment

Exclusion criteria:
Use of oral gabapentin Pregnancy or lactation Concomitant kidney, liver, blood, thyroid, and psychiatric diseases or any other systemic disease that may cause pruritus

Age
From **6 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **19**
More than 1 sample in each individual
Number of samples in each individual: **2**
Two pruritic areas of skin are selected in each patient, one for medication and the other for placebo

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
In each patient, two pruritic areas are defined for the use of medication or a placebo. The type of intervention in each lesion remains unclear to both, the patients and the researcher until the end of the study. Products are delivered within completely similar 50 gr containers. Containers are identified with adhesive labels (A or B) so the subjects and investigators are not aware of the kind of treatment in each lesion (double-blind design).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Local Ethics Committee, Shiraz University of Medical Sciences, Setad Squ., Zand Blvd., Shiraz.

City
Shiraz

Province
Fars

Postal code
7176913861

Approval date
2021-07-14, 1400/04/23

Ethics committee reference number
IR.SUMS.MED.REC.1400.210

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
itching

Timepoint
Baseline and at the end of treatment (end of 6th week)

Method of measurement
Leuven_itch_scale

2

Description
Pruritic area size

Timepoint
Baseline and at the end of treatment (end of 6th week)

Method of measurement
(Length × width) ÷ 2

3

Description
Erythema
Timepoint
Baseline and at the end of treatment (end of 6th week)
Method of measurement
Examination: absent (0), mild (pink-1), moderate (pink to red-2), severe (red-3)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group receives topical Gabapentine 10%(plus 10%Glycerine in base of cold cream)formulized and prepared in Dr.Rastegar pharmacy on the assigned side 3 times daily for 6 weeks .
Category
Treatment - Drugs

2

Description
Control group: Control group uses base cream(١٠% glycerin in cold cream) on the assigned side 3times daily for 6 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faghihi hospital
Full name of responsible person
Nasrin Saki
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Dermatology clinic, Faghihi hospital, Setad Sque., Zand Blvd., Shiraz.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Position
Dermatology resident
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Person responsible for updating data

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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
Not applicable