

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation of the Effect of Topical Gabapentin in Itching in Patients with Macular Amyloidosis; A pilot study

#### Protocol summary

Itching severity; pigmentation rate; patient satisfaction; topical side effects of drug use

#### Study aim

Determination of the effect of topical gabapentin on itching in patients with macular amyloidosis

#### Design

This study is a randomized clinical trial with parallel groups (right and left side of lesion in each patient) by using placebo control group. Sample size is 40 patients by simple sampling.

#### Settings and conduct

This study is performed on patients with macular amyloidosis referred to dermatology clinics of Isfahan University of Medical Sciences. Patients are enrolled after obtaining informed consent form and if they have inclusion criteria after examination. A checklist is completed for each participant including demographic data, family history, history of drug use, systemic diseases and age at onset of skin lesions, etc.

Photography is done before treatment and in all of sessions in standard and fixed conditions. Each side of the lesion will be allocated to the main drug and placebo group and the other side to the gabapentin treatment group. The drug is taken twice a day and as a thin layer of topical medication. The patients will be evaluated for outcomes.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Clinical diagnosis of macular amyloidosis; Age range from 18 to 50 years; Corneal skin lesion in the back; No history of treatment in the past 6 months; Consent to attend to this study; No history of gabapentin allergy; No interference with other patient medications Exclusion criteria: Pregnancy; Breastfeeding; Inability to take medication; Renal failure; Depression; Neurological diseases

#### Intervention groups

Each side of the lesion in each individual is randomly allocated to receive the main drug and the placebo, and the other side (left or right) is selected as the drug group.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131119015455N4**

Registration date: **2020-01-26, 1398/11/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-01-26, 1398/11/06**

Update count: **0**

##### Registration date

2020-01-26, 1398/11/06

##### Registrant information

##### Name

Bahareh Abtahi-Naeini

##### Name of organization / entity

Skin Diseases and leishmaniasis research Center, Isfahan University of Medical Sciences, Isfahan, Ir

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-21, 1398/08/30

##### Expected recruitment end date

2020-09-19, 1399/06/29

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the Effect of Topical Gabapentin in Itching in Patients with Macular Amyloidosis; A pilot study

**Public title**

Effect of Topical Gabapentin in Itching

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Clinical diagnosis of macular amyloidosis Age range from 18 to 50 years Corneal skin lesion in the back No history of treatment in the past 6 months Consent to attend to this study No history of gabapentin allergy No interference with other patient medications

**Exclusion criteria:**

Pregnancy Breastfeeding Inability to take medication Renal failure Depression Neurological diseases

**Age**

From **18 years** old to **50 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

Corneal lesions on the back of each patient that one side is assigned to the main drug and placebo group and the other to the gabapentin treatment group.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is performed using software to allocate each side of the lesion to the main drug and placebo group and the other side to the gabapentin treatment group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

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Research and Technology Deputy of Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan

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8174673461

**Approval date**

2019-11-03, 1398/08/12

**Ethics committee reference number**

IR.MUI.MED.REC.1398.366

**Health conditions studied****1****Description of health condition studied**

macular amyloidosis

**ICD-10 code**

E85.8

**ICD-10 code description**

Other amyloidosis

**Primary outcomes****1****Description**

Itching severity

**Timepoint**

Before intervention and 2, 4, 6 weeks after intervention with topical Gabapentin.

**Method of measurement**

12- item severity pruritus scale and 4- item itching questioner

**2****Description**

Pigmentation rate

**Timepoint**

Before intervention and 2, 4, 6 weeks after intervention with Gabapentin

**Method of measurement**

Photo finder system

**Secondary outcomes****1****Description**

Patient satisfaction

**Timepoint**

Six month after treatment

**Method of measurement**

patient satisfaction Visual Analogue Scale score

**2****Description**

Topical side effects of drug use

**Timepoint**

Four, 8, 12 weeks and 6 months after intervention

**Method of measurement**

Clinical evaluation

**Intervention groups****1****Description**

Intervention group: One side of the lesion (left or right) on the back of each patient is randomly allocated to receive topical Gabapentin in gel based with 0.06 concentration (Temad and Farabi company) that is used as a thin layer and twice a day for 3 months.

**Category**

Treatment - Drugs

**2****Description**

Control group: The other side of the lesion (left or right) on the back of each patient is selected to receive placebo in gel based (Timad company) that is used as a thin layer and twice a day.

**Category**

Placebo

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

Dermatology clinic of Al-Zahra hospital, Isfahan

**Full name of responsible person**

Dr. Bahar Saffar

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Department of Pathology, Al-Zahra hospital, Soffeh Boulevard, Isfahan

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**2****Recruitment center****Name of recruitment center**

Skin Diseases and Leishmaniasis Research Center

**Full name of responsible person**

Dr. Zabihollah Shahmordi

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

Esfahan University of Medical Sciences

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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**

Esfahan 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**

Esfahan University of Medical Sciences  
**Full name of responsible person**  
Dr Bahar Saffar  
**Position**  
Resident  
**Latest degree**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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## Person responsible for updating data

### Contact

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

**Full name of responsible person**  
Dr. Bahareh Abtahi  
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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

Primary outcome data can be shared.

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

Starting 6 months after publication

### To whom data/document is available

People working in academic institutions

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

Descriptive analysis is allowed to report on data

### From where data/document is obtainable

Bahareh Abtahi Skin Diseases and Leishmaniasis  
Research Center, Isfahan, Iran Email:  
bahareh.abtahi@med.mui.ac.ir

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

The request is discussed in the Center Committee and  
after approval, the data is submitted to the applicant  
over a period of approximately one month.

### Comments