

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

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

Skin Diseases and Leishmaniasis Research Center

Full name of responsible person

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

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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
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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:
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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