

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of the effect of TCA (20%) trichloroacetic acid and topical combination of steroid and tretinoin in macular amyloidosis; a double blind clinical trial.

#### Protocol summary

##### Study aim

A Comparison of the Effect of 20% Trichloroacetic Acid (TCA) and the Combination of Topical Steroid and Tretinoin in the Treatment of Macular Amyloidosis

##### Design

This study is a parallel group, double-blind randomized clinical trial study. The phase of the study is 3. The sample number is 20.

##### Settings and conduct

This study is done at Dermatology Clinic of Sabzevar Vasei Hospital. Given that macular amyloidosis is a sympathetic disease, TCA 20% will be used for one side and the topical combination of steroid and tretinoin will be used for the other side of the body. A month later, patients will be referred to a doctor who is not aware of the intervention and the pigmentation changes will be evaluated and recorded. This will be done for three one-month courses.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with macular amyloidosis referred to dermatology clinic of Vasei Hospital in Sabzevar; being at the age of 25 to 45 years; satisfaction to participate the study.

##### Intervention groups

Given that macular amyloidosis is a sympathetic disease, TCA 20% will be used for one side and the topical combination of steroid and tretinoin will be used for the other side of the body.

##### Main outcome variables

cutaneous pigmentation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180102038188N1**

Registration date: **2018-06-13, 1397/03/23**

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

Last update: **2018-06-13, 1397/03/23**

Update count: **0**

##### Registration date

2018-06-13, 1397/03/23

##### Registrant information

###### Name

Edriss Arezoumand

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 5423 0263

###### Email address

arezomande90@medsab.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-05, 1397/03/15

##### Expected recruitment end date

2018-09-06, 1397/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of TCA (20%) trichloroacetic acid and topical combination of steroid and tretinoin in macular amyloidosis; a double blind clinical trial.

##### Public title

The effect of TCA (20%) trichloroacetic acid and topical combination of steroid and tretinoin in macular amyloidosis

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Patients with macular amyloidosis referring to dermatology clinic of Sabzevar Vasei Hospital Being at the age of 25 to 45 years Satisfaction to participate in the study

##### **Exclusion criteria:**

#### **Age**

From **25 years** old to **45 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

- Participant
- Outcome assessor

#### **Sample size**

Target sample size: **20**

More than 1 sample in each individual

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

Given that macular amyloidosis is a sympathetic disease, TCA 20% will be used for one side and the topical combination of steroid and tretinoin will be used for the other side of the body.

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Block randomization method based on gender and using PASS software will be used in this study.

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

In this double-blind study, patients and outcome evaluators who is dermatologist will be kept blind.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Sabzevar University of Medical Sciences

###### **Street address**

Sabzevar University of Medical Sciences, Tohid Shahr

###### **City**

Sabzevar

###### **Province**

Razavi Khorasan

###### **Postal code**

9613873137

###### **Approval date**

2018-03-05, 1396/12/14

###### **Ethics committee reference number**

IR.MEDSAB.REC.1396.160

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Macular amyloidosis

##### **ICD-10 code**

##### **ICD-10 code description**

### **Primary outcomes**

#### **1**

##### **Description**

Cutaneous pigmentation

##### **Timepoint**

0, 1, 2 and 3 months later

##### **Method of measurement**

Checklist completed by dermatologist

### **Secondary outcomes**

#### **1**

##### **Description**

-

##### **Timepoint**

-

##### **Method of measurement**

-

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Given that the disease is a sympathetic disease, on one side of the body, TCA 20% will be used. This intervention will be done for three one month periods.

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Control group: In this group, routine treatment including topical composition containing triamcinolone 15 grams and tretinoin 15 grams) will be performed for the other side of the back. This intervention will be done for three one month periods.

**Category**  
Treatment - Drugs

**Type of organization providing the funding**  
Academic

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Vasei Hospital  
**Full name of responsible person**  
Maryam Karabi  
**Street address**  
Vasei Hospital; Tawhid City Road  
**City**  
Sabzevar  
**Province**  
Razavi Khorasan  
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9613873137  
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+98 21 4401 8317  
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arezomande90@medsab.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Sabzevar University of Medical Sciences  
**Full name of responsible person**  
Dr. Fereshteh Ghorat  
**Street address**  
Vasei Hospital, Towhid Shahr Road  
**City**  
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**Province**  
Razavi Khorasan  
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**Phone**  
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**Email**  
arezomande90@medsab.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Sabzevar 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**

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Sabzevar University of Medical Sciences  
**Full name of responsible person**  
Maryam Karabi  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
Vasei Hospital, Towhid Shahr Road  
**City**  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Sabzevar University of Medical Sciences  
**Full name of responsible person**

Maryam Karabi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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**Province**

Razavi Khorasan

**Postal code**

9613873137

**Phone**

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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**

Undecided - It is not yet known if there will be 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**

In this study, only a portion of the data will be shared, such as the primary and secondary outcomes.

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

Get started since 1398

**To whom data/document is available**

This study will be available to all people in the community.

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

-

**From where data/document is obtainable**

Dr Maryam Karabi, Sabzevar University of Medical Sciences.

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

Contact with Research and Technology Unit of Sabzevar University of Medical Sciences

**Comments**

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