

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
Postal code
9613873137
Phone
+98 21 4401 8317
Email
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
sabzevar
Province
Razavi Khorasan
Postal code
9613873137
Phone
+98 21 4401 8317
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
sabzevar
Province
Razavi Khorasan
Postal code
9613873137
Phone
+98 21 4401 8317
Email
arezomande90@medsab.ac.ir

Person responsible for scientific 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
Sabzevar
Province
Razavi Khorasan
Postal code
9613873137
Phone
+98 21 4401 8317
Email
arezomande90@medsab.ac.ir

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

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Dermatology

Street address

Vasei Hospital, Towhid Shahr Road

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+98 21 4401 8317

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arezomande90@medsab.ac.ir

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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