Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of efficacy of intralesional injection of tranexamic acid and topical fluocinolone acetonide ointment 0.025% in treatment of macular amyloidosis: a randomized, single-blinded, split clinical trial

Protocol summary

Study aim

Comparison of efficacy of intralesional injection of tranexamic acid and topical fluocinolone acetonide ointment 0.025% in treatment of macular amyloidosis

Design

The present study is an open-label, parallel-group, randomized (using coin toss) clinical trial involving 21 patients.

Settings and conduct

This open-label randomized clinical trial included 21 macular amyloidosis patients from Valiasr Hospital in Arak. Participants were randomly assigned (via coin toss) to one of two treatment arms(Tranexamic acid therapy, Fluocinolone acetonide therapy). Final outcomes were then compared between the two treatment groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Presence of relatively symmetrical macular amyloidosis lesions in specified areas; informed consent for study participation. Exclusion criteria: History of any treatment for the removal of macular amyloidosis within 6 weeks before the start of the study; Pregnancy and lactation; ; active infections; significant systemic diseases; smoking, alcohol consumption, or drug abuse; history of multiple miscarriages; History of allergy to tranexamic acid or fluocinolone.

Intervention groups

Intervention group (Tranexamic Acid): Participants receive intralesional injections of tranexamic acid at a concentration of 4 mg/mL, administered every two weeks for a total of five sessions. The solution is combined with lidocaine prior to injection. Control group (Fluocinolone): Participants apply 0.025% fluocinolone acetonide ointment topically twice daily. In case of corticosteroid-related side effects, treatment is temporarily discontinued and resumed once symptoms resolve.

Main outcome variables

Pigmentation improvement , pigmentation pattern, pigmentation percentage, skin thickness, itching level, patient satisfaction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N38**
Registration date: **2025-07-06, 1404/04/15**
Registration timing: **prospective**

Last update: **2025-07-06, 1404/04/15**
Update count: **0**

Registration date

2025-07-06, 1404/04/15

Registrant information

Name

Amin Haji seyyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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amin.medstu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-11, 1404/04/20

Expected recruitment end date

2025-12-11, 1404/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of intralesional injection of tranexamic acid and topical fluocinolone acetonide ointment 0.025% in treatment of macular amyloidosis: a randomized, single-blinded, split clinical trial

Public title

Comparison of the effectiveness of intralesional tranexamic acid injection and topical fluocinolone acetonide ointment in the treatment of macular amyloidosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of macular amyloidosis lesions between the shoulder blades, on the arms, thighs, or above the chest, appearing relatively symmetrical on both sides. Having provided informed consent to participate in the study.

Exclusion criteria:

History of any treatment aimed at removing macular amyloidosis lesions within 6 weeks prior to the start of the study Pregnancy Breastfeeding Active skin infection Systemic diseases (such as diabetes, kidney, heart, respiratory, liver diseases, or severe anemia) Bleeding disorders Connective tissue diseases Genodermatoses Smoking Alcohol consumption Drug abuse History of recurrent miscarriages No medication (including nutritional supplements) use History of allergy to tranexamic acid or fluocinolone

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **21**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method using coin flipping is employed to determine the side of the body to receive either intralesional tranexamic acid injection or fluocinolone ointment for each participant. Given that the trial design is split-body and intra-individual, each participant's body is divided into symmetrical right and left sides, and the interventions are applied independently to each side. The randomization process is carried out as follows: 1- Before the intervention begins, each participant is given a standard coin with two distinct sides (e.g., heads and tails). 2- The participant is instructed that if the coin shows heads, the right side will receive tranexamic acid and the left side will receive fluocinolone ointment. If the coin shows tails, the reverse will be applied. 3- The coin is flipped by the participant and the outcome is immediately recorded in the clinical data form. 4- Once assigned, the treatment sides remain fixed throughout the study with no crossover. 5- To ensure procedural symmetry, the dosage, application method, session timing, and outcome evaluation are performed identically and simultaneously on both sides of the body. Due to the intra-individual nature and the small sample size, coin flipping is considered a practical and appropriate method for simple randomization in this setting. No software or web-based tool will be used for this randomization.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Research Deputy, Arak University of Medical Sciences, Basij Square, Sardasht District, Arak, Iran

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Province

Markazi

Postal code

3848176941

Approval date

2025-02-23, 1403/12/05

Ethics committee reference number

IR.ARAKMU.REC.1403.373

Health conditions studied

1

Description of health condition studied

Macular amyloidosis

ICD-10 code

E85

ICD-10 code description

Amyloidosis

Primary outcomes

1

Description

Pigmentation improvement

Timepoint

At the beginning of the intervention, before each therapy session, and two weeks after the last therapy session.

Method of measurement

Pigmentation Scoring System

2

Description

Pigmentation pattern

Timepoint

At the beginning of the intervention, before each therapy session, and two weeks after the last therapy session.

Method of measurement

Examination of the lesion’s waviness

3

Description

Pigmentation percentage

Timepoint

At the beginning of the intervention, before each therapy session, and two weeks after the last therapy session.

Method of measurement

Pigmentation Percentage Scoring System

4

Description

Skin thickness

Timepoint

At the beginning of the intervention, before each therapy session, and two weeks after the last therapy session.

Method of measurement

Examination for the presence of lesion lichenification

5

Description

Itching level

Timepoint

At the beginning of the intervention, before each therapy session, and two weeks after the last therapy session.

Method of measurement

Visual Analog Scale

6

Description

Patient satisfaction

Timepoint

At the beginning of the intervention, before each therapy session, and two weeks after the last therapy session.

Method of measurement

Patient Satisfaction Scoring System

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Treatment in this project is carried out using 0.025% Fluocinolone Acetonide ointment, manufactured by the Iranian company “Tehran Chemie.” The treatment involves gently rubbing the ointment onto the affected area in a quantity just enough to be absorbed by the skin without leaving any residue. This procedure is performed twice daily. Patients are advised that if they experience any symptoms indicating corticosteroid side effects (such as skin thinning, telangiectasia, etc.), they should temporarily stop using the ointment and resume treatment only after the symptoms have resolved.

Category

Treatment - Drugs

2

Description

Intervention Group 2: In the area of tranexamic acid injection, injections are administered using two units of insulin from a solution prepared with tranexamic acid at a concentration of 4 mg/mL, spaced 1 centimeter apart. The injections are performed biweekly for a total of five sessions. The tranexamic acid ampoule, manufactured by the Iranian company Aburaihan, has a concentration of 500 mg in 5 mL. Accordingly, 0.08 mL of the tranexamic acid solution is drawn using an insulin syringe and mixed with lidocaine up to the 100-unit mark on the syringe.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Valiasr Hospital

Full name of responsible person

Dr. Mina Mirnezami

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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Dr. Nooshin Bagherani

Position
Associate professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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General Practitioner

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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

After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long

Access will be from 09/21/2025 to 09/21/2028 for 3 years.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Academic researchers, university professors, or students who wish to use the data from this study may do so after obtaining permission from the relevant individuals mentioned. They are allowed to use the data for meta-analyses or other related review studies. Additionally, upon request, the information may be used as a basis for future research or to address questions and uncertainties. Any use of this study's data requires proper citation of the names and affiliations of the responsible individuals involved in the study.

From where data/document is obtainable

Academic researchers and university professors can request access to and use of the data from Zahra Rafiei by contacting her via message or email. Contact Information: Zahra Rafiei: Phone: +98 918 482 5248 Email: Zahrar4554@gmail.com Address: Arak, Shahid Shiroudi Street, Vali Asr Hospital

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

If a request for data or study documentation is submitted by researchers or relevant institutions, a formal written request must first be provided. This should include the purpose of use, the type of data requested, and the level of access required. The request will be reviewed by the principal investigator and the research ethics team. Upon approval, anonymized and de-identified data will be shared with the requester. All procedures will strictly adhere to confidentiality principles and ethical research regulations.

Comments