Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of efficacy and safety of intra lesional tranexamic acid injection versus topical Kligman’s formula application in the treatment of macular amyloidosis

Protocol summary

Study aim
Comparison of efficacy and safety of intra lesional tranexamic acid injection versus topical Kligman’s formula application in the treatment of macular amyloidosis

Design
A double blind randomized clinical trial in 40 patients

Settings and conduct
This study will be conducted in Hazrate Rasoule Akram Hospital, Tehran, Iran. 40 macular amyloidosis patients will randomly divided to tranexamic acid (4 mg/ml intradermally)and Kligman (a tip of finger topical Kligman each night) groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age range 18 to 50 years, suffering from macular amyloidosis Exclusion criteria: pregnant or lactating women, history of cardiovascular disease, Keloid patients, patients taking anticoagulants, any allergy to the study drugs, history of bleeding disorder, topical treatment three months before entering the study, no consent to participate in the study

Intervention groups
Tranexamic acid group: Six sessions of treatment every two weeks are given by the physician as an intra lesional tranexamic acid. Kligman group: Apply a tip of finger topical Kligman each night for 12 weeks

Main outcome variables
Skin darkness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150529022468N5**
Registration date: **2019-07-30, 1398/05/08**
Registration timing: **registered_while_recruiting**
Last update: **2019-07-30, 1398/05/08**
Update count: **0**

Registration date
2019-07-30, 1398/05/08

Registrant information

Name
Mohammadreza Ghassemi

Name of organization / entity
Iran University of Medical Scienses

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-22, 1397/09/01

Expected recruitment end date
2019-09-21, 1398/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of efficacy and safety of intra lesional tranexamic acid injection versus topical Kligman’s formula application in the treatment of macular amyloidosis

Public title
Comparison of tranexamic acid versus Kligman’s

application in the treatment of macular amyloidosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18 to 50 years Suffering from macular amyloidosis

Exclusion criteria:

Pregnant or lactating women History of cardiovascular disease Keloid patients Patients taking anticoagulants Any allergy to the study drugs History of bleeding disorder Topical treatment three months before entering the study No consent to participate in the study

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

To select patients randomly, 40 pieces of paper will be numbered from 1 to 40. For each patient one of the papers will be taken in random order. If the number is paired, the patient will be in the tranexamic acid group, and if the number is Odd in the Kligman group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be evaluated by a physician. This physician will be blind to the grouping of patients. In addition, the data analyzer will be blind to the grouping of patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN

City

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Province

Tehran

Postal code

1449614535

Approval date

2019-07-02, 1398/04/11

Ethics committee reference number

IR.IUMS.FMD.REC.1398.138

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

Skin darkness

Timepoint

4, 8 and 12 weeks after start and 3 months after finishing the treatment

Method of measurement

The Visioface device, the third physician's opinion, and the patient's opinion.

Secondary outcomes

1

Description

drug side effects

Timepoint

4, 8 and 12 weeks after start and 3 months after finishing the treatment

Method of measurement

Check list

2

Description

Onset of therapeutic effect

Timepoint

4, 8 and 12 weeks after start and 3 months after finishing the treatment

Method of measurement

The Visioface device, the third physician's opinion, and the patient's opinion. The doctor's and patient opinion will be announced through the following options: 1. No response (no amelioration) 2. poor response (amelioration less than 25%) 3. average response (amelioration from 25% to 50%) 4. good response (amelioration from 50% to 75%) 5. very good response (amelioration by more than 75%)

3

Description
Continuity of drug effect
Timepoint
4, 8 and 12 weeks after start and 3 months after finishing the treatment
Method of measurement
The Visioface device, the third physician's opinion, and the patient's opinion. The doctor's and patient opinion will be announced through the following options: 1. No response: no amelioration 2. poor response: amelioration less than 25% 3. average response: amelioration from 25% to 50% 4. good response: amelioration from 50% to 75% 5. very good response: amelioration by more than 75%

Intervention groups

1

Description
Intervention group: tranexamic acid. Six sessions of treatment every two weeks are given by the physician as an intra lesional tranexamic acid. Each session, 0.1 cc of 4 mg / ml tranexamic acid will be injected interdermally with a 30-G needle and at a distance of 1 cm to an area of 10*10 cm which covers the entire lesion area.
Category
Treatment - Drugs

2

Description
Intervention group: Kligman (with hydroquinone 4.0%, tretinoin 0.05%, fluocinolone acetonide 0.01%, vit c 500mg formula). Apply a tip of finger topical Kligman on a dry and clean skin each night for 12 weeks and do not rinse at least 4 hours after application.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Dermatology of Hazrate Rasoule Akram Hospital
Full name of responsible person
Mohammadreza Ghassemi
Street address
Hazrate Rasoule Akram Hospital, Niayesh St,Satarkhan Av, Tehran, IRAN
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mohammadreza Ghassemi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All of information without name
When the data will become available and for how long
1 years after publish
To whom data/document is available
Researchers
Under which criteria data/document could be used
All of patients information without their name
From where data/document is obtainable
Study researcher: Mohammadreza Ghasemi
What processes are involved for a request to access data/document
sending email to the researcher: ghassemi.mr@iums.ac.ir
Comments