

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 Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 2040

Email address

ghassemi.mr@iums.ac.ir

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

Tehran

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

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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 scientific inquiries

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Person responsible for updating data

Contact

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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 Ghassemi

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

sending email to the researcher:

ghassemi.mr@iums.ac.ir

Comments