Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Efficacy of intralesional injection of tranexamic acid versus topical tretinoin 0.05% in treatment of solar lentigines on dorsum of the hands: a controlled randomized clinical trial

Protocol summary

Study aim

Efficacy of intralesional tranexamic acid injection versus topical tretinoin 0.05% in the treatment of solar lentigo on the back of the hand

Design

A controlled, parallel-group, randomized, phase 2 clinical trial on 54 patients. Coin tossing is used for randomization.

Settings and conduct

Our study is a randomized clinical trial conducted on 54 volunteers with solar lentigo on the hands. In each patient, we will assign intervention and control status based on the affected side (right or left). In the control group, topical tretinoin cream 0.05% is prescribed once a night, and in the intervention group, tranexamic acid at a concentration of 4 mg/ml diluted with lidocaine is injected into the lesion every two weeks for up to 5 sessions.The number of lentigo macules in the groups is assessed and recorded before each treatment session and 2 weeks after the last session.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 35 years; both sexes; absence of active skin infections in the area of tranexamic acid injections; absence of any systemic disease; absence of vascular diseases and events such as embolism and vascular thrombosis; No history of any treatment for solar lentigo for 6 weeks prior to study entry; No pregnancy; No breastfeeding Exclusion criteria: Severe allergic reaction; Unwillingness to continue treatment

Intervention groups

In the treatment with tretinoin cream, the patient is instructed to apply the cream to the entire back of the hand and in an amount that does not leave a trace on the skin.In the area of tranexamic acid injection, injections of two insulin units of a solution prepared from tranexamic acid at a concentration of 4 mg/ml are made intradermally in each lesion. The injections are made every 2 weeks for up to 5 sessions.

Main outcome variables

Number of lentigo macules; overall lentigo improvement score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250424065457N1**
Registration date: **2025-05-12, 1404/02/22**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-12, 1404/02/22**
Update count: **0**

Registration date

2025-05-12, 1404/02/22

Registrant information

Name

Alireza Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-05, 1404/02/15

Expected recruitment end date

2026-05-05, 1405/02/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of intralesional injection of tranexamic acid versus topical tretinoin 0.05% in treatment of solar lentigines on dorsum of the hands: a controlled randomized clinical trial

Public title
Studying the effect of intralesional injection of tranexamic acid in the treatment of solar lentigo
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 35 years Presence of relatively symmetrical solar lentigo lesions on the backs of the hands
Exclusion criteria:
pregnancy breastfeeding History of any treatment for solar lentigo within 6 weeks prior to the start of the study Active skin infections in the area where tranexamic acid injections were given Vascular diseases and accidents such as embolism and vascular thrombosis
Age
From **35 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
For each individual, the treatment side with tranexamic acid injection or tretinoin cream was determined based on a coin toss. The treatment side with tranexamic acid injection or cream remained constant throughout the study.
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
Faculty of Medicine, University Complex of the Great Prophet (PBUH), Basij Square, Sardasht
City
Arak
Province
Markazi
Postal code
6341738481
Approval date
2025-04-21, 1404/02/01
Ethics committee reference number
IR.ARAKMU.REC.1404.002

Health conditions studied

1

Description of health condition studied
solar lentigo
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Number of lentigo macules
Timepoint
The number of lentigo macules was assessed before each treatment session and 2 weeks after the last session for both intervention and control groups and recorded in the patient information form.
Method of measurement
Counting the number of lentigo macules

2

Description
Lentigo Overall Improvement Score
Timepoint
The overall improvement score of solar lentigo was assessed before each treatment session from the second session onwards and 2 weeks after the last session for both intervention and control groups and recorded in the patient information form.
Method of measurement
Scoring system

3

Description
Subjective assessment of lesion healing
Timepoint
Subjective assessment of lesion improvement is assessed before each treatment session from the second

session onwards and 2 weeks after the last session for both intervention and control groups and recorded in the patient information form.

Method of measurement

Scoring system

4

Description

Assessing complications and pain severity in patients

Timepoint

From the second session onwards, before each session, patients are asked about the side effects of both methods and this is recorded in a questionnaire. Also, from the first session, during the injections, they are asked about the intensity of pain and this is calculated based on the Visual Analogue Scale and recorded in the questionnaire.

Method of measurement

question

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tranexamic acid at a concentration of 4 mg/ml diluted with lidocaine is injected locally into the lesion every two weeks for up to 5 sessions. Injections are performed intradermally into each lesion at a rate of 2 microunits of insulin.

Category

Treatment - Drugs

2

Description

Control group: Topical tretinoin cream 0.05% is prescribed as a common treatment for solar lentigo once a night.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Alireza Abbasi

Street address

Valiasr Hospital, Valiasr Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Behzad Khansari Nejad

Street address

Department of Research and Technology, Arak University of Medical Sciences, Prophet Muhammad (PBUH) University Complex, Basij Square

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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

Alireza Abbasi

Position

student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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No. 15, Ordibehesht 5 Alley, Phase 2, Shahid Beheshti Town
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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
All data can be shared after individuals are de-identified.
When the data will become available and for how long
Access period starts 12 months after results are published.
To whom data/document is available
Scientific and academic researchers
Under which criteria data/document could be used
Having a specific and legitimate purpose, ensuring data security and limiting access to data to researchers.
From where data/document is obtainable
To receive the documents, send an email to alirezaabbasi2017@gmail.com.
What processes are involved for a request to access data/document
Researchers must sign formal agreements that clearly outline the terms of access and use of information, including clauses such as confidentiality, information security, and how data will be used. Open in Google Translate
Comments