Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating the Efficacy of Tranexamic Acid Mesotherapy in Treatment of Periorbital Wrinkles: a Randomized Control Trial

Protocol summary

Study aim
Determine the efficacy and safety of intradermal tranexamic acid mesotherapy compared with placebo for the improvement of periorbital wrinkles

Design
A randomized, double-blind, placebo-controlled, parallel-group (split-face design), phase 2 clinical trial on 20 patients (40 periorbital sides). For randomization Sealed Envelope System was used.

Settings and conduct
This study is conducted at the Dermatology Clinic of Shahid Faghihi Hospital, Shiraz University of Medical SciencesPatients receive 4 weekly periocular injections of tranexamic acid on one side and placebo contralaterally. It is double-blind; patients, clinical evaluators, and image analysts are masked using third-party identically coded syringes

Participants/Inclusion and exclusion criteria
Patients aged 30–60 years with periorbital wrinkles (WSRS≥2). Inclusion criteria: written consent; no cosmetic procedures in past 3 months or eye creams in past week. Exclusion criteria: pregnancy; lactation; coagulopathies; history of thromboembolism;

Intervention groups
Intervention Group: Intradermal micro-injections of tranexamic acid (100 mg/mL) into one periorbital side at 0.1 mL per puncture point spaced 1 cm apart (total volume 1.0–1.5 mL per session) using a 30G needle, administered weekly for 4. Control Group: Intradermal micro-injections of normal saline into the contralateral periorbital side with identical injection technique, spacing, volume (0.1 mL per puncture; total 1.0–1.5 mL per session), and 30G needle, administered weekly for 4 consecutive sessions.

Main outcome variables
Change in periorbital wrinkle volume measured by VisioFace at 1-month post-treatment; change in clinical wrinkle severity based on WSRS; change in wrinkle area and depth via VisioFace analysis; patient satisfaction score using a 5-point Likert scale; incidence of local and systemic adverse events

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260619069876N1**
Registration date: **2026-10-01, 1405/07/09**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-01, 1405/07/09**
Update count: **0**

Registration date
2026-10-01, 1405/07/09

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-30, 1405/07/08

Expected recruitment end date
2027-02-27, 1405/12/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the Efficacy of Tranexamic Acid Mesotherapy in Treatment of Periorbital Wrinkles: a Randomized Control Trial

Public title
Tranexamic Acid Mesotherapy in Treatment of Periorbital Wrinkles

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Clinically visible periorbital wrinkles (grade ≥2 on WSRS) Age between 30 and 60 years, any gender No cosmetic or rejuvenation procedures (laser, fillers, botulinum toxin, PRP, microneedling) within the past 3 months No topical anti-wrinkle or periocular cream use during the past week Willingness to refrain from any cosmetic procedures during the study period Ability to comply with study schedule and provide informed consent

Exclusion criteria:
Pregnancy or lactation Current use of anticoagulants, hormonal contraceptives, or topical periocular anti-wrinkle creams History of malignancy, deep vein thrombosis, pulmonary embolism, or cerebrovascular accident Severe systemic illness or coagulation disorders Heavy smoking or excessive occupational UV exposure Any hypersensitivity to TXA or injection components Participant request to discontinue participation Occurrence of severe adverse events or intolerance to injections Non-compliance with study protocol (missed >1 consecutive session)

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Side allocation (right vs. left periorbital area receiving intradermal tranexamic acid vs. normal saline) will be determined using a permuted block randomization method with a fixed block size of 4 and an allocation ratio of 1:1. The allocation sequence will be generated using a validated web-based randomization service, Sealed Envelope (www.sealedenvelope.com), with a pre-specified documented random seed to ensure reproducibility. To ensure robust allocation concealment, the randomization key will be securely retained by an independent third party who is not involved in participant recruitment, clinical administration, or outcome evaluation. This individual will prepare identical 1-mL insulin syringes pre-filled with either tranexamic acid or normal saline, labeled uniformly with neutral codes as "Side A" and "Side B" corresponding to sequentially numbered, opaque, sealed envelopes. The treatment allocation will remain completely concealed from the participant, the injector, the outcome assessor, and the image analysis investigator until study completion and database lock.

Blinding (investigator's opinion)
Double blinded

Blinding description
This clinical trial is designed as a double-blind study where both participants and outcome assessors remain blinded to treatment allocation: Participant Blinding: Participants will remain completely unaware of which periorbital side receives tranexamic acid (TXA) and which side receives normal saline. Both sides will undergo identical intradermal injection protocols using indistinguishable 1-mL insulin syringes with 30-gauge needles, equal injection volumes (0.1 mL per puncture), identical 1-cm spacing, and uniform injection techniques. Outcome Assessor Blinding: The two independent board-certified dermatologists evaluating periorbital wrinkles via the Wrinkle Severity Rating Scale (WSRS) on standardized photographs will be fully blinded to treatment allocation. Furthermore, 3D digital images acquired by the VisioFace system will be independently coded and analyzed by an investigator blinded to intervention assignments. Syringe Preparation & Masking: To eliminate administration bias, pre-filled syringes containing TXA or saline will be prepared by an independent third party who is not involved in treatment delivery or outcome evaluation. Syringes will be identically labeled with neutral designations ("Side A" and "Side B") matching the concealed allocation log, ensuring blinding is maintained until database lock and unblinding.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Zand Street

City
Shiraz

Province

Fars

Postal code

7134846114

Approval date

2026-02-07, 1404/11/18

Ethics committee reference number

IR.SUMS.MED.REC.1404.605

Health conditions studied

1

Description of health condition studied

Periorbital wrinkles

ICD-10 code

L57.8

ICD-10 code description

Other skin changes due to chronic exposure to nonionizing radiation

Primary outcomes

1

Description

Change in periorbital wrinkle volume compared to baseline

Timepoint

Baseline and 1 month after the completion of the 4th treatment session

Method of measurement

3D digital imaging and software-based quantification using the VisioFace system (measured in px^3) within a standardized region of interest (ROI)

Secondary outcomes

1

Description

Change in periorbital wrinkle area and area percentage

Timepoint

Baseline, weekly during the 4 treatment sessions, and 1 month post-treatment

Method of measurement

Quantitative surface analysis using the VisioFace 3D imaging system (measured in px^2 and area percentage).

2

Description

Change in periorbital wrinkle depth

Timepoint

Baseline, weekly during treatment visits, and 1 month post-treatment

Method of measurement

Automated quantitative wrinkle depth measurement using calibrated VisioFace 3D imaging (in mm or pixels)

3

Description

Clinical severity of periorbital wrinkles

Timepoint

Baseline and 1 month after the final treatment session

Method of measurement

Independent evaluation of standardized clinical photographs by two blinded dermatologists using the 5-point Wrinkle Severity Rating Scale (WSRS, grades 1 to 5).

4

Description

Patient satisfaction with periorbital wrinkle improvement and aesthetic outcome

Timepoint

1 month following the completion of treatment

Method of measurement

Self-administered questionnaire using a 5-point Likert scale (ranging from 1 = Very Dissatisfied to 5 = Very Satisfied)

5

Description

Incidence, nature, and severity of treatment-related local and systemic adverse events

Timepoint

At each weekly injection visit (Weeks 1 to 4) and at the 1-month post-treatment follow-up.

Method of measurement

Clinical examination and patient reporting recorded on standardized Case Report Forms (CRFs), assessing local complications (erythema, edema, ecchymosis, papules) and ocular symptoms.

Intervention groups

1

Description

Intervention group: Intradermal injection (mesotherapy) of tranexamic acid (1 mL ampoules at a concentration of 100 mg/mL) is performed on one side of the periorbital area (randomly assigned to either the right or left side). Injections are administered using a 1 mL insulin syringe and a fine 30-gauge needle, delivering a dose of 0.1 mL per injection point at 1 cm intervals within the designated periorbital area (total volume of 1 to 1.5 mL per side per session). This procedure is carried out by a dermatologist over four consecutive sessions at one-week intervals.

Category

Treatment - Other

2

Description

Control group: Intradermal micro-injections of normal saline (0.9% sodium chloride as placebo) into the contralateral periorbital side (split-face design). Injections are administered using 1-mL insulin syringes with 30-gauge needles at a volume of 0.1 mL per puncture point spaced approximately 1 cm apart within

the standardized periorbital region of interest (total volume 1.0–1.5 mL per side per session), utilizing a technique identical to the intervention side. The procedure is performed weekly for 4 consecutive sessions by a board-certified dermatologist.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Dermatology clinic of Shahid Faghihi Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Phone
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Email
vcrdep@sums.ac.ir
Web page address

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Armin Gorjian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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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
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
Data/Document Title: Clinical data and VisioFace 3D images Sharing Details: Anonymized individual participant data (IPD)—including demographic characteristics, WSRS clinical scores, and VisioFace 3D images—will be made available upon reasonable request to the corresponding author following the publication of the main study.

When the data will become available and for how long
Access begins 6 months after publication of the study results and will remain available for a period of 2 years.

To whom data/document is available
Academic researchers and faculty members affiliated with recognized universities or medical research institutions with an approved protocol and defined research purpose.

Under which criteria data/document could be used
Purpose: Permitted exclusively for secondary statistical analyses, systematic reviews, and meta-analyses related to skin rejuvenation. Conditions: Provision of a scientifically approved protocol with institutional ethics clearance; execution of a formal Data Use Agreement (DUA); strict prohibition of any re-identification attempts; prohibition of commercial use; and mandatory citation of the original publication.

From where data/document is obtainable
Applicants must submit their written request and proposal via email to the student author of the thesis: Contact Person: Dr. Armin Gorjian Address: Dermatology Clinic, Shahid Faghihi Hospital, Zand Street, Shiraz, Shiraz University of Medical Sciences Email: Armingorjian1996@gmail.com Phone: 00987132351087

What processes are involved for a request to access data/document
Submission of formal request, approved protocol, and ethics clearance to the corresponding author via email. Protocol review by the research team within 2–3 weeks.Upon approval, signing of a formal Data Use Agreement (DUA) by the applicant within 1 week.Delivery of de-identified data via secure email within 1 week post-signing (total expected timeframe: 3–5 weeks).

Comments