Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative Study of Hyaluronic Acid Microneedle patches versus Topical Hyaluronic Acid for Improvement of Facial Skin Hydration and Elasticity

Protocol summary

Study aim
Comparative Study of Hyaluronic Acid Microneedle patches vs. Topical Hyaluronic Acid for Improvement of Facial Skin Hydration and Elasticity

Design
A Two-Arm, phase 2, randomized, active controlled, split face, clinical study. sample size is 20. The study is not randomized. Randomization is done by simple randomization using a blind card.In this way, the name of the formulation is written on the same card. A card is selected randomly for each region.

Settings and conduct
The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy, 20 Cases of aging skin, fine lines and wrinkles around the eyes with mild to moderate grade will be selected and enrolled in the study after signing consent form. Before intervention, 4 and 12 weeks after using changing in skin elasticity ,skin hydration and depth, area and volume of periorbital area will be measured. This study is one-way blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Male or female aged 30-60 years People with aging skin, fine lines and wrinkles around the eyes with grades 3 and 4 (mild to moderate) according to the Fitzpatrick classification Signed informed consent knowingly Exclusion criteria: Sensitivity to hyaluronic acid or standard formulation ingredients Using invasive skin treatments such as laser or Botox in the past 6 months. Active skin infection or disease. Pregnancy or lactation

Intervention groups
Intervention group: Injectable Hyaluronic acid microneedles . Contains: Hyaluronic Acid: A mix of low and high molecular weights. Once in a week for 4 weeks. Control group: Topical treatment with Vitalier hyaluronic skin serum, 30 ml, daily

Main outcome variables
Skin elasticity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190210042676N46**
Registration date: **2025-08-10, 1404/05/19**
Registration timing: **prospective**

Last update: **2025-08-10, 1404/05/19**
Update count: **0**

Registration date
2025-08-10, 1404/05/19

Registrant information
Name
Aniseh Samadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8897 2220
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-09-23, 1404/07/01
Expected recruitment end date
2026-02-20, 1404/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparative Study of Hyaluronic Acid Microneedle patches versus Topical Hyaluronic Acid for Improvement of Facial Skin Hydration and Elasticity

Public title
Comparative Study of Hyaluronic Acid Microneedle patches vs. Topical Hyaluronic Acid
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Male or female aged 30-60 years People with aging skin, fine lines and wrinkles around the eyes with grades 3 and 4 (mild to moderate) according to the Fitzpatrick classification Signed informed consent knowingly
Exclusion criteria:
Sensitivity to hyaluronic acid or standard formulation ingredients Using invasive skin treatments such as laser or Botox in the past 6 months. Active skin infection or disease. Pregnancy or lactation
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked

- Care provider

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done by simple randomization using a blind card.In this way, the name of the formulation is written on the same card. A card is selected randomly for each region.
Blinding (investigator's opinion)
Single blinded
Blinding description
In case of assessor blinding, the randomization list is given to a third person. Assignment of the formulation to the treatment sites of participants is made after receiving the code of randomization by researcher.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of The Institute of Pharmaceutical Sciences of Tehran University of Medical Science
Street address
Unit 1-219, 2nd floor,The Institute of Pharmaceutical Sciences, Faculty of Pharmacy,16 Azar Avenue 1-219
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2025-08-03, 1404/05/12
Ethics committee reference number
R.TUMS.TIPS.REC.1404.055

Health conditions studied

1

Description of health condition studied
periorbital wrinkle, dark circle
ICD-10 code
R23.4
ICD-10 code description
Changes in skin texture

Primary outcomes

1

Description
Skin elasticity
Timepoint
Before intervention, 4 and 12 weeks after intervention
Method of measurement
Cutometery

Secondary outcomes

1

Description
Depth, area and volume of periorbital area
Timepoint
Before intervention, 4 and 12 weeks after intervention
Method of measurement
Visioface camera

2

Description
Skin hydration changes of periorbital area
Timepoint
Before intervention, 4 and 12 weeks after intervention
Method of measurement
Corneometery by MPA580

Intervention groups

1

Description
Intervention group: Injectable Hyaluronic acid microneedles . Contains: Hyaluronic Acid: A mix of low and high molecular weights. Once in a week for 4 weeks.
Category
Treatment - Drugs

2

Description
Control group: Topical treatment with Vitalier hyaluronic skin serum, 30 ml, daily
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Center for research and training in skin diseases and leprosy,Tehran University of Medical Sciences
Full name of responsible person
Aniseh Samadi
Street address
No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue
City
Tehran
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Postal code
1416613675
Phone
+98 21 8897 0658
Email
dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohamadhossein Yazdi
Street address
Unit 4, Fifth Floor, University Research Centers Building, North Kargar
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1417993344
Phone
+98 21 8898 7255
Email
mh-yazdi@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Aniseh Samadi
Position
Manger of clinical study unit
Latest degree
Ph.D.
Other areas of specialty/work
Dermatology
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Person responsible for scientific inquiries

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Full name of responsible person
Azin Ayatollahi
Position
Dermatologist
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Maryam Ahmadi

Position
Research Expert

Latest degree
Master

Other areas of specialty/work
Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable