Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical evaluation of the efficacy and safety of Luxiva brand skin mesotherapy solution for rejuvenation and improvement of facial skin elasticity and hydration

Protocol summary

Study aim
Clinical evaluation of the efficacy and safety of Luxiva brand skin mesotherapy solution for rejuvenation and improvement of facial skin elasticity and hydration

Design
Phase II single group. before -after, clinical study

Settings and conduct
The study will be conducted in center for research and training in skin diseases and leprosy. participants will be treated in 4 Injection sessions with Luxiva brand skin mesotherapy solution. assessment will be performed before first treatment, one month after the last injection (day 90) and 2 months after the last injection (day 120) including improvement assessment using digital face photography and measurement the skin hydration and skin elasticity.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 35 and 60 years old; present visible signs of skin ageing symptoms mainly skin dryness skin roughness; loss of elasticity and appearance of fine lines; possibility to accompany the visit plans and study process; signing an informed consent form and agreed to follow up. Exclusion criteria: previous treatment with hyaluronic acid fillers in the facial area within the past year; experience with RF, rejuvenation lasers or intense pulsed light in the past 6 months; systemic diseases affecting skin health such as collagen vascular diseases, diabetes, hypothyroidism, as well as liver and renal failure.

Intervention groups
4 sessions with 4 cc sterile solution of Luxiva injection mesotherapy. The intervals for the first three injections are done at the beginning of every two weeks and the fourth injection, one month after the third injection. Luxiva injection solution is sterile and contains hyaluronic acid 20 mg/vial amino acid alanine, arginine, etc.

Main outcome variables
Skin elasticity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150101020514N25**
Registration date: **2023-11-12, 1402/08/21**
Registration timing: **prospective**

Last update: **2023-11-12, 1402/08/21**
Update count: **0**

Registration date
2023-11-12, 1402/08/21

Registrant information

Name
Alireza Firooz

Name of organization / entity
Tehran University of Medical Science

Country
Iran (Islamic Republic of)

Phone
+98 21 8897 8190

Email address
firozali@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-05-21, 1403/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical evaluation of the efficacy and safety of Luxiva brand skin mesotherapy solution for rejuvenation and improvement of facial skin elasticity and hydration

Public title
Clinical evaluation of the efficacy and safety of Luxiva brand skin mesotherapy solution for rejuvenation of facial skin
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 35 and 60 years old Present visible signs of skin ageing symptoms mainly skin dryness skin roughness, loss of elasticity and appearance of fine lines Possibility to accompany the visit plans and study process. Signing an informed consent form and agreed to follow up.
Exclusion criteria:
Previous treatment with hyaluronic acid fillers in the facial area within the past year Experience with RF, rejuvenation lasers or intense pulsed light in the past 6 months Systemic diseases affecting skin health such as collagen vascular diseases, diabetes, hypothyroidism, as well as liver and renal failure. History of systemic use of skin-related medicine such as glucocorticoids, isotretinoin, immunomodulators and hormonal medicine in the past 3 months Currently pregnant or lactating Smoking in the past two years
Age
From **35 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
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
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2023-11-11, 1402/08/20
Ethics committee reference number
IR.TUMS.TIPS.REC.1402.100

Health conditions studied

1

Description of health condition studied
Skin hydration
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Skin elasticity
Timepoint
Before intervention, one month after the last injection (day 90) and 2 months after the last injection (day 120)
Method of measurement
Cutometery

Secondary outcomes

1

Description
Stratum corneum hydration
Timepoint
Before intervention, one month after the last injection (day 90) and 2 months after the last injection (day 120)
Method of measurement
Corneometry by MPA 580

2

Description
Skin condition for signs of skin aging including clear lines and wrinkles
Timepoint

Before intervention, one month after the last injection (day 90) and 2 months after the last injection (day 120)

Method of measurement

Using GAIS scale

Intervention groups

1

Description

Intervention group: 4 sessions with 4 cc sterile solution of Luxiva injection mesotherapy. The intervals for the first three injections are done at the beginning of every two weeks and the fourth injection, one month after the third injection. Luxiva injection solution is sterile and contains hyaluronic acid 20 mg/vial amino acid alanine, arginine, etc.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

center for research and training in skin diseases and leprosy

Full name of responsible person

Aniseh Samadi

Street address

No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.

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Province

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1416613675

Phone

+98 21 8897 0658

Email

dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Atra Zist Arai Company

Full name of responsible person

Amir Maghsoudi

Street address

No. 110, West Bahman St., Sepehr Industrial Estate

City

Nazarabad

Province

Alborz

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3331495900

Phone

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Email

info@atrazistaray.co.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Atra Zist Arai Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

Superviser of clinical study unit

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz

Position

Professor of dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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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