

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 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

Cutometry

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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1416613675

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+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

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+98 919 100 4001

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

Supervisor of clinical study unit

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

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aniseh_samadi@yahoo.com

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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firozali@sina.tums.ac.ir

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