

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Safety and efficacy assessment of injectable gel containing stabilized hyaluronic acid with Perleux® brand, in order to rejuvenate and improve facial skin elasticity and hydration

Protocol summary

Study aim

Determining of Safety and efficacy assessment of injectable gel containing stabilized hyaluronic acid with Perleux® brand, in order to rejuvenate and improve facial skin elasticity and hydration

Design

The study is a phase 2 before-after clinical trial. The sample size is 20. The study was not randomized.

Settings and conduct

The study will be conducted in center for research and training in skin diseases and leprosy, Tehran university of medical sciences. Participants will be treated in one injection sessions with injectable gel containing stabilized hyaluronic acid with Perleux® brand. Assessment will be performed before first treatment, 8 and 16 week after treatment including improvement assessment using digital face photography and measurement the skin hydration and skin elasticity.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 35 -60 years old men and women. The presence of visible signs of skin aging mainly dry skin, skin roughness, loss of elasticity and clear lines and wrinkles. Have signed the informed consent form and agree to a 6-month follow-up. Exclusion criteria: Previous hyaluronic acid (HA)-based dermal filler treatment(s) injected within the last 12 months prior to enrollment, History of radiofrequency (R-F), rejuvenation lasers or intense pulsed light in the past 6 months, Pregnancy or lactation

Intervention groups

One injection with 2 cc stabilized hyaluronic acid with Perleux® brand. The product is 2cc prefilled sterilized syringe containing: 32 mg Hyaluronic Acid with high molecular weight+ 32 mg Hyaluronic Acid with low molecular weight from sodium hyaluronic acid salt in 2 ml soluble physiological buffer sodium chloride.

Main outcome variables

Skin elasticity (R0, R2, R5) measured in right cheek

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150101020514N17**

Registration date: **2022-12-06, 1401/09/15**

Registration timing: **prospective**

Last update: **2022-12-06, 1401/09/15**

Update count: **0**

Registration date

2022-12-06, 1401/09/15

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

2022-12-22, 1401/10/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Safety and efficacy assessment of injectable gel containing stabilized hyaluronic acid with Perleux® brand, in order to rejuvenate and improve facial skin elasticity and hydration

Public title
Safety and efficacy assessment of injectable gel with Perleux® brand, in order to rejuvenate facial skin

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
35 -60 years old men and women The presence of visible signs of skin aging mainly dry skin, skin roughness, loss of elasticity and clear lines and wrinkles. Have signed the informed consent form and agree to a 6-month follow-up
Exclusion criteria:
Previous hyaluronic acid (HA)-based dermal filler treatment(s) injected within the last 12 months prior to enrollment History of radiofrequency (R-F), rejuvenation lasers or intense pulsed light in the past 6 months
Pregnancy or lactation

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
2022-11-26, 1401/09/05

Ethics committee reference number
IR.TUMS.TIPS.REC.1401.083

Health conditions studied

1

Description of health condition studied

Skin Hydration

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Skin elasticity (R0, R2, R5) measured in right cheek

Timepoint

Before intervention, 8 and 16 weeks later

Method of measurement

By cutometer probe of MPA 580(Multi Probe Adaptor) device

Secondary outcomes

1

Description

Thickness and density of dermis

Timepoint

Before intervention, 8 and 16 weeks later

Method of measurement

Skin ultrasound

2

Description

Trans Epidermal Water Lost (TEWL) measured in right cheek

Timepoint

Before intervention, 8 and 16 weeks later

Method of measurement

By TEWA probe of MPA 580(Multi Probe Adaptor) device

Intervention groups

1

Description

Intervention group: One injection with 2 ccstabilized

hyaluronic acid with Perleux® brand. The product is 2cc prefilled sterilized syringe containing: 32 mg Hyaluronic Acid with high molecular weight+ 32 mg Hyaluronic Acid with low molecular weight from sodium hyaluronic acid salt in 2 ml soluble physiological buffer sodium chloride.

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) St., Taleqani Ave.

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Email

dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zist orchid pharmed Company

Full name of responsible person

Pegah Nehzati

Street address

No 42,Atar squer, Atar street, Valie-asr street,Vanak squer

City

Tehran

Province

Tehran

Postal code

1994766411

Phone

+98 21 4347 3000

Email

ask@orchidpharmed.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zist orchid pharmed 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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

MD and Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

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No. 415, Taleqani Ave.

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Email

dermalab@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz

Position

Dermatologist and professor of Tehran University of Medical Sciences.

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

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Phone

+98 21 8897 2220

Email

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Dermatology

Street address

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Tehran

Postal code

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Phone

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