

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Safety and effectiveness assessment of Lunafill Ultra intradermal injectable gel containing hyaluronic acid (24mg/ml) and lidocaine 0.3% for correcting nasolabial folds. Phase II, before after clinical study

Protocol summary

Study aim

Safety and efficacy assessment of Lunafill ultra intradermal injectable gel for correction of moderate to severe nasolabial folds

Design

Phase II, before after clinical study

Settings and conduct

The study will be conducted in Center for research and training in skin diseases and leprosy. Before intervention face photography will be taken from participants using digital camera and Visioface camera for determination the severity of nasolabial folds, according to Allergan scale. Skin ultrasound also will performed on nasolabial folds. One intradermal injection with Lunafill Ultra will be performed on each nasolabial fold. The assessment will be repeated right after intervention and 2 weeks, 3 and 6 months later. Subjects' satisfaction and adverse effect will be recorded in each follow up visit

Participants/Inclusion and exclusion criteria

18 -65 years old men and women, with moderate to severe nasolabial folds, without any cosmetic facial procedures during last 3 months, with no allergy to lidocaine, hyaluronic acid products and no auto immune or immune deficiency diseases. No pregnant and lactating

Intervention groups

One injection with 1-2 cc Lunafill ultra intradermal injectable gel in each nasolabial fold. The product is 1cc prefilled sterilized syringe containing: Hyaluronic Acid gel, 24 mg; Lidocaine hydrochloride, 3 mg; Phosphate buffer (pH 7.2), 1 m.

Main outcome variables

Severity of nasolabial folds according to Allergan grading

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150101020514N11**

Registration date: **2021-03-17, 1399/12/27**

Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

Registration date

2021-03-17, 1399/12/27

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

2021-04-05, 1400/01/16

Expected recruitment end date

2021-05-06, 1400/02/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and effectiveness assessment of Lunafill Ultra intradermal injectable gel containing hyaluronic acid (24mg/ml) and lidocaine 0.3% for correcting nasolabial folds. Phase II, before after clinical study

Public title
Safety and effectiveness of Lunafill Ultra intradermal injectable gel for correcting nasolabial folds

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 18 -65 years old men and women Moderate to severe nasolabial folds Signing the infirmed consent form
Exclusion criteria:
 Previous hyaluronic acid (HA)-based dermal filler treatment(s) injected within the last 12 months prior to enrollment Cosmetic facial procedures (chemical peel, laser, radio frequency, dermabrasion, ablative or non-ablative procedures), Botox) in the lower 2/3 of the face, within 3 month prior to study entry Planning to undergo any of these procedures at any time during the study Allergy or sensitivity to lidocaine, hyaluronic acid products Active inflammation, infection, cancerous or pre-cancerous lesion or unhealed wound in the NLF region Current treatment with anti-coagulation therapy or use of non-steroidal anti-inflammatory drugs or other substances known to increase coagulation time within 10 days of undergoing study injections People prone to hypertrophic scar formation History of ant auto immune or immune deficiency diseases or using any immune suppressive drug Pregnancy and breast feeding

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

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 Tehran University of Medical Sciences

Street address

Room 105 , 5th floor, Central construction of Tehran University of Medical Sciences, Ghods intersection, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-03-15, 1399/12/25

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.1271

Health conditions studied

1

Description of health condition studied

Skin aging

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of nasolabial folds

Timepoint

Before intervention and right after that and 2 weeks, 3 and 6 months later

Method of measurement

5 scale Allergan phot numeric grading

Secondary outcomes

1

Description

Depth, area and volume of nasolabial fold

Timepoint

Before intervention and right after that and 2 weeks, 3 and 6 months later

Method of measurement

Visioface camera

2

Description

Thickness and density of dermis

Timepoint

Before intervention and 2 weeks and 6 months later

Method of measurement

Skin ultrasound

Intervention groups

1

Description

Intervention group: one injection with 1-2 cc Lunafill ultra intradermal injectable gel in each nasolabial fold. The product is 1cc prefilled sterilized syringe containing: Hyaluronic Acid gel, 24 mg Lidocaine hydrochloride, 3 mg Phosphate buffer (pH 7.2), 1 m

Category

Treatment - Devices

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

415, Taleghani Avenue.

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 street, Boostan alley, Kavosieh Ave

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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

Industry

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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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

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firozali@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

Researcher

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available