Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Safety and effectiveness assessment of Fiorage L. gel produced by Orchid Pharmed company for nasolabial folds correction

Protocol summary

Study aim
Safety and efficacy assessment of Fiorage L 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 Fiorage L 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 Fiorage L 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: **IRCT20150101020514N12**
Registration date: **2021-06-29, 1400/04/08**
Registration timing: **prospective**

Last update: **2021-06-29, 1400/04/08**
Update count: **0**

Registration date
2021-06-29, 1400/04/08

Registrant information

Name
Alireza Firooz

Name of organization / entity
Tehran University of Medical Science

Country
Iran (Islamic Republic of)

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+98 21 8897 8190

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firozali@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2021-08-23, 1400/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Safety and effectiveness assessment of Fiorage L. gel produced by Orchid Pharmed company for nasolabial folds correction

Public title
Safety and effectiveness assessment of Fiorage L. gel for nasolabial folds correction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18 -65 years old men and women Moderate to severe nasolabial folds based onAllergan criteria The opportunity to accompany the visit programs and study process. Signing the infirmed 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 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
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 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
2021-06-20, 1400/03/30
Ethics committee reference number
IR.TUMS.TIPS.REC.1400.052

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 photonumeric 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 Fiorage L 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 and mannitol (pH 7.2), up to 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.

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Tehran

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Tehran

Postal code
1416613675

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+98 21 8897 2220

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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, Kavoosieh Ave

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1994766411

Phone
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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
Persons

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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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 Univercity of Medical Sciences.

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

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

Not applicable

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