Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

A single-arm, before- after clinical study to evaluate the safety and efficacy of Inshape X® intradermal filler containing 150mg poly-L-lactic acid (NanoDaru Pajuhan Pardis) for correction of moderate to severe nasolabial folds

Protocol summary

Study aim

Evaluate the safety and efficacy of Inshape X® intradermal filler containing 150mg poly-L-lactic acid (NanoDaru Pajuhan Pardis) for correction of moderate to severe nasolabial folds.

Design

Single group, phase 2, before -after clinical study. sample size is 30. The study is not randomized.

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 perform on nasolabial folds. One intradermal injection with Inshape X® intradermal filler made by NanoDaru Pajuhan Pardis Company will be performed on each nasolabial fold. The assessment will be repeated one, 3, 6 and12 months after intervention. Subjects' satisfaction and adverse effect will be recorded in each follow up visit.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18–65-year-old men and women, Moderate to severe nasolabial folds based on Allergan criteria. The opportunity to accompany the visit programs and study process. Signing the informed consent form and agree to a 6-month follow-up. Exclusion criteria: History of type 1 allergic reactions or anaphylaxis reactions, Previous allergy to filler and lidocaine ingredients, History of hypertrophic and colloid scars or bleeding disorders in the nasolabial region

Intervention groups

receiving a subcutaneous dose of Inshape-x-scalp suspension (poly-L-lactic acid of Pardis Nano Darou Pazhouhan Pharmaceutical Company) containing 150 mg, using one of the linear threading, Fanning, Serial puncture, and Cross hatch techniques, according to the researcher's opinion.

Main outcome variables

Severity of nasolabial folds according to Allergan grading

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150101020514N26**
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)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date
2024-02-20, 1402/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A single-arm, before- after clinical study to evaluate the safety and efficacy of Inshape X® intradermal filler containing 150mg poly-L-lactic acid (NanoDaru Pajuhan Pardis) for correction of moderate to severe nasolabial folds

Public title
evaluate the safety and efficacy of Inshape X® intradermal filler
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18–65-year-old men and women Moderate to severe nasolabial folds based on Allergan criteria. The opportunity to accompany the visit programs and study process. Signing the informed consent form and agree to a 6-month follow-up.
Exclusion criteria:
History of type 1 allergic reactions or anaphylaxis reactions Previous allergy to filler and lidocaine ingredients History of hypertrophic and colloid scars or bleeding disorders in the nasolabial region Active inflammatory processes, infection, lesion (cancerous/noncancerous) in the nasolabial region Pregnancy and lactation
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
2023-11-10, 1402/08/19
Ethics committee reference number
IR.TUMS.TIPS.REC.1402.097

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 4 weeks later
Method of measurement
5 scale Allergan photo numeric grading

Secondary outcomes

1

Description
Severity of nasolabial folds
Timepoint
Before intervention, 3, 6 and 12 months later
Method of measurement
5 scale Allergan photo numeric grading

2

Description
Severity of nasolabial folds
Timepoint
Before intervention, 1, 3, 6 and 12 months later
Method of measurement
Based on GAIS scale compared to base mode

3

Description
Depth, area and volume of nasolabial fold
Timepoint
Before intervention, 1, 6 and 12 months later
Method of measurement
Visioface camera

Intervention groups

1

Description
Intervention group: receiving a subcutaneous dose of inshape-x-scalp suspension (poly-L-lactic acid of Pardis Nano Darou Pazhouhan Pharmaceutical Company) containing 150 mg, using one of the linear threading, Fanning, Serial puncture, and Cross hatch techniques, according to the researcher's opinion. Preparation of each vial is done using 8ml sterile water. In order to pain reduction, 1 ml of lidocaine 2% will be added to the prepared suspension before injection and the final suspension volume will be 9 ml.
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) Street, Taleqani Avenue
City
Tehran
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Postal code
1416613675
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+98 21 8897 0658
Email
dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nano Darou Pajouhan Pardis Company
Full name of responsible person
Navid Goodarzi
Street address
No. 18, Between Motahari Street and South Etaati St., Marzdaran Blvd.
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Tehran
Province
Tehran
Postal code
1464736143
Phone
+98 912 635 4536
Email
info@nanodaru.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nano Darou Pajouhan Pardis 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
Manger of clinical study unit
Latest degree
Ph.D.
Other areas of specialty/work
Dermatology
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No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue
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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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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Research Expert

Latest degree
Master

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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