Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Evaluating the safety and effectiveness of injectable gel with the Perjunse brand, for correcting nasolabial folds, before and after single clinical trial

Protocol summary

Study aim
Evaluating the safety and effectiveness of injectable gel with the Perjunse brand, for correcting 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 Perjunse will be performed on each nasolabial fold. The assessment will be repeated right after intervention and 2, 12 and 24 weeks later. Subjects' satisfaction and adverse effect will be recorded in each follow up visit.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 18 -65 years old men and women, with moderate to severe nasolabial folds, the opportunity to accompany the visit programs and study process.
Exclusion criteria: Previous hyaluronic acid (HA)-based dermal filler treatment(s) injected within the last 12 months; Cosmetic facial procedures (chemical peel, laser, radio frequency, dermabrasion, ablative or non-ablative procedures), Botox) in the lower 2/3 of the face, within last 3 months.

Intervention groups
Intervention group: One injection with 1-2 cc Perjunse gel in each nasolabial fold. Perjunse is a sterile physiological solution, without fever microbial agent. The active ingredient of this product is 24 mg/ml cross-linked hyaluronic acid with non-animal origin.

Main outcome variables
Severity of nasolabial folds according to Allergan grading

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150101020514N24**
Registration date: **2023-10-16, 1402/07/24**
Registration timing: **prospective**

Last update: **2023-10-16, 1402/07/24**
Update count: **0**

Registration date
2023-10-16, 1402/07/24

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
2023-10-22, 1402/07/30

Expected recruitment end date
2024-01-20, 1402/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluating the safety and effectiveness of injectable gel with the Perjunse brand, for correcting nasolabial folds, before and after single clinical trial

Public title
Safety and effectiveness of injectable gel with the Perjunse brand

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:
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 months prior to study entry Planning to undergo any of these procedures at any time during the study Any cosmetic facial procedures during last 3 months Allergy to gram positive bacteria protein, gel ingredients Auto immune or immune deficiency diseases Pregnancy 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
2023-10-08, 1402/07/16

Ethics committee reference number
IR.TUMS.TIPS.REC.1402.085

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 intervention and 2, 12 and 24 weeks later

Method of measurement
5 scale Allergan photo numeric grading

Secondary outcomes

1

Description
Depth, area and volume of nasolabial fold

Timepoint
Before intervention and right after intervention and 2, 12 and 24 weeks later

Method of measurement
Visioface camera

2

Description
Thickness and density of dermis

Timepoint
Before intervention and right after intervention and 2, 12 and 24 weeks later

Method of measurement
Skin ultrasound

Intervention groups

1

Description
Intervention group: Intervention group: One injection with 1-2 cc Perjunse gel in each nasolabial fold. Perjunse is a sterile physiological solution, without fever microbial agent. The active ingredient of this product is 24 mg/ml cross-linked hyaluronic acid with non-animal origin.
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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1416613675
Phone
+98 21 8897 0658
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dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pars Fardad Nano Technology Company
Full name of responsible person
Forzandeh Zare Nejad
Street address
Unit 13, 5th floor, No. 9, corner of North Farzin, Baqerkhan St., Sattarkhan St.
City
Tehran
Province
Tehran
Postal code
1441763737
Phone
+98 21 6690 8553
Email
farrokh.najafi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Pars Fardad Nano Technology 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
Manger of clinical study unit
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 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

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