

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the safety and effectiveness of injectable gel with the Perjune 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 Perjune 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 Perjune 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 Perjune gel in each nasolabial fold. Perjune 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)

Phone

+98 21 8897 8190

Email address

firozali@tums.ac.ir

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	Name of ethics committee
Evaluating the safety and effectiveness of injectable gel with the Perjune brand, for correcting nasolabial folds, before and after single clinical trial	Ethics committee of The Institute of Pharmaceutical Sciences of Tehran University of Medical Science
Public title	Street address
Safety and effectiveness of injectable gel with the Perjune brand	Unit 1-219, 2nd floor, The Institute of Pharmaceutical Sciences, Faculty of Pharmacy, 16 Azar Avenue
Purpose	City
Treatment	Tehran
Inclusion/Exclusion criteria	Province
Inclusion criteria:	Tehran
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	Postal code
Exclusion criteria:	1417613151
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	Approval date
Age	2023-10-08, 1402/07/16
From 18 years old to 65 years old	Ethics committee reference number
Gender	IR.TUMS.TIPS.REC.1402.085
Both	
Phase	Health conditions studied
2	<u>1</u>
Groups that have been masked	Description of health condition studied
No information	Skin aging
Sample size	ICD-10 code
Target sample size: 30	ICD-10 code description
Randomization (investigator's opinion)	
N/A	Primary outcomes
Randomization description	<u>1</u>
Blinding (investigator's opinion)	Description
Not blinded	Severity of nasolabial folds
Blinding description	Timepoint
Placebo	Before intervention and right after intervention and 2, 12 and 24 weeks later
Not used	Method of measurement
Assignment	5 scale Allergan photo numeric grading
Single	
Other design features	Secondary outcomes
	<u>1</u>
Secondary Ids	Description
empty	Depth, area and volume of nasolabial fold
Ethics committees	Timepoint
<u>1</u>	Before intervention and right after intervention and 2, 12 and 24 weeks later
Ethics committee	Method of measurement
	Visioface camera
	<u>2</u>
	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 Perjune gel in each nasolabial fold. Perjune 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

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 0658

Email

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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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
Tehran University of Medical Sciences
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