Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the safety and effectiveness of injectable gel with the ATP POUYA brand, for correcting nasolabial folds

Protocol summary

Study aim
Evaluating the safety and effectiveness of injectable gel with the ATP POUYA brand, for correcting 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 perform on nasolabial folds. One intradermal injection with ATP POUYA 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
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 gram positive bacteria protein, gel ingredients and no auto immune or immune deficiency diseases. No pregnant and lactating

Intervention groups
One injection with 1-2 cc ATP POUYA injectable gel in each nasolabial fold. ATP POUYA is a pure, disposable, viscose and transparent gel. The active ingredient of this product is stabilized sodium 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: **IRCT20150101020514N20**
Registration date: **2023-02-18, 1401/11/29**
Registration timing: **prospective**

Last update: **2023-02-18, 1401/11/29**
Update count: **0**

Registration date
2023-02-18, 1401/11/29

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
2023-05-22, 1402/03/01

Expected recruitment end date
2023-08-23, 1402/06/01

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 ATP POUYA brand, for correcting nasolabial folds

Public title
Safety and effectiveness assessment of ATP POUYA 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 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.

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

2023-02-14, 1401/11/25

Ethics committee reference number

IR.TUMS.TIPS.REC.1401.115

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: One injection with 1-2 cc ATP POUYA injectable gel in each nasolabial fold. ATP POUYA is a pure, disposable, viscose and transparent gel. The active ingredient of this product is stabilized sodium 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, Tehran University of Medical Sciences

Full name of responsible person
Aniseh Samadi

Street address
415, Taleghani Avenue.

City
Tehran

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Tehran

Postal code
1416613675

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+98 21 8897 2220

Email
dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Pouya Teb Tools Company

Full name of responsible person
Nader Noshirvani Dizaji

Street address
Unit 8, No. 18, 2nd St., Yousef Abad

City
Tehran

Province
Tehran

Postal code
3738114789

Phone
+98 912 426 1875

Email
info@abzartebpouya.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Pouya Teb Tools 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 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

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