Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

A single-arm, before- after clinical study to evaluate the safety and efficacy of Intella dermal filler (produced by Espad Pharmed Darou Co.) for correction of moderate to severe nasolabial folds

Protocol summary

Study aim
Evaluation of safety and efficacy of Intella dermal filler (produced by Espad Pharmed Darou Co.) 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 Intella will be performed on each nasolabial fold. The assessment will be repeated right after intervention and 2, 4, 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 year old men and women, Moderate to severe nasolabial folds based on Allergan criteria, The opportunity to accompany the visit programs and study process. Exclusion criteria: History of type 1 allergic reactions or anaphylaxis reaction, Pregnancy or lactation

Intervention groups
One injection with 1-2 ml Intella brand gel in each nasolabial folds. Intella is a pyrogen-free, viscous, opaque, injectable, semi-solid, latex-free and biodegradable dermal filler gel.

Main outcome variables
Severity of nasolabial folds according to Allergan grading

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150101020514N27**
Registration date: **2024-01-24, 1402/11/04**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-24, 1402/11/04**
Update count: **0**

Registration date
2024-01-24, 1402/11/04

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
2024-01-21, 1402/11/01

Expected recruitment end date
2024-04-03, 1403/01/15

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 Intella dermal filler (produced by Espad Pharmed Darou Co.) for correction of moderate to severe nasolabial folds

Public title
Clinical study to evaluate the safety and efficacy of Intella dermal filler for correction of nasolabial folds
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 reaction Previous hyaluronic acid-based dermal filler injected within the last 12 months prior to enrollment. History of hypertrophic and keloid scars or bleeding disorders in the nasolabial region Active inflammatory processes, infection, lesions (cancerous/non-cancerous) in the nasolabial region History of autoimmune diseases/immune deficiency or use of immunosuppressive medicines during the 6 months before entering the study or during the study Pregnancy or 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
2024-01-02, 1402/10/12
Ethics committee reference number
IR.TUMS.TIPS.REC.1402.145

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, 4, 12 and 24 weeks later
Method of measurement
5 scale Allergan photo numeric grading

Secondary outcomes

1

Description
Number of people with at least one grade of reduction in the severity of both nasolabial folds
Timepoint
Before intervention and 3 and 6 months later
Method of measurement
scale Allergan photo numeric grading

2

Description
Depth, area and volume of nasolabial fold
Timepoint
Before intervention ,1 ,3 and 6 months later
Method of measurement
Visioface camera

3

Description
Thickness and density of dermis
Timepoint

Before intervention ,1 and 6 months later

Method of measurement

Skin ultrasound

Intervention groups

1

Description

Intervention group: One injection with 1-2 ml Intella brand gel produced by Espad Pharmed company in each nasolabial folds. Intella is a pyrogen-free, viscous, opaque, injectable, semi-solid, latex-free and biodegradable dermal filler gel. Ingredients: calcium hydroxyapatite microspheres with a diameter of 25-45 microns (55.7%), cross-linked sodium hyaluronate gel (20 mg per ml), lidocaine hydrochloride (3 mg per ml), phosphate buffer

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

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1416613675

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dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

ESpadpharmed company

Full name of responsible person

Hooshyar Gholami

Street address

Unit 5, 3rd floor, No. 56, Azimi St., Nafisi St., Ekbatan town

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Email

info@espadpharmed.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

ESpadpharmed 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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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