

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

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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

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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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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Phone

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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