Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the Safety and Effectiveness of Inovo Sense Smile and Inovo Sense Style Intradermal Injectable Gel for Correcting Moderate to Severe Nasolabial Folds

Protocol summary

Study aim

Evaluation of the Safety and Effectiveness of Inovo Sense Smile and Inovo Sense Style Intradermal Injectable Gel for Correcting Moderate to Severe Nasolabial Folds

Design

An interventional, randomized, non-blinded, non-placebo, single-study, treatment-intent, phase 2 clinical trial on 30 patients.

Settings and conduct

The study will be conducted in the dermatology clinic of Razi Hospital. Before the intervention, face photography will be taken from participants using a Visioface camera، and the intensity of the wrinkles is scored based on the 5-point photonumeric Allergan scale from 0 (no wrinkles) to 4 (very deep wrinkles). For each person with a score of 3, one injection with 1 ml of Inovo Sense Smile gel, and for each person with a score of 4, one injection with 1 ml of Inovo Sense Style gel (produced by Khosro Medisa Teb) intradermally in the NLF will be done. The assessments will be repeated immediately after the intervention, 2 weeks and 3 months later. Subjects' satisfaction and adverse effect will be recorded in each follow-up visit.

Participants/Inclusion and exclusion criteria

30 -65 years old women and men, with moderate to severe nasolabial folds, without any cosmetic facial procedures during the last 3 months, without any allergy to lidocaine, hyaluronic acid and no autoimmune or immune deficiency diseases. No pregnant and breastfeeding

Intervention groups

Injection of Inovo Sense Smile and Inovo Sense Style Intradermal gel in the nasolabial folds, the products are in the 1 ml prefilled sterilized syringe containing: Inovo Sense Smile: Hyaluronic Acid gel 20 mg; Lidocaine hydrochloride, 0.3% ; Phosphate buffer (pH 7), 1 ml Inovo Sense Style: Hyaluronic Acid gel, 23 mg; Lidocaine hydrochloride, 0.3% ; Phosphate buffer (pH 7), 1 ml

Main outcome variables

Severity of nasolabial folds based on the 5-point photonumeric Allergan scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220723055530N1**
Registration date: **2022-07-27, 1401/05/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-27, 1401/05/05**
Update count: **0**

Registration date

2022-07-27, 1401/05/05

Registrant information

Name

Amirhooshang Ehsani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5563 0223

Email address

ehsanih@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-26, 1401/05/04

Expected recruitment end date

2022-08-01, 1401/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Safety and Effectiveness of Inovo Sense Smile and Inovo Sense Style Intradermal Injectable Gel for Correcting Moderate to Severe Nasolabial Folds

Public title

Assessment of the Results of Inovo Sense Smile and Inovo Sense Style Filler Injections to Correction Nasolabial Folds

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

30 -65 Years old men and women with moderate to severe nasolabial folds Signing the informed consent form

Exclusion criteria:

History of a cosmetic procedure in the lower 2/3 of the face during the last three months Previous allergy to Hyaluronic Acid or Lidocaine Presence of inflammation, active infection, unhealed old wound, and skin lesions in the NLF region People prone to hypertrophic scar formation History of autoimmune or immune deficiency diseases Pregnancy or breastfeeding

Age

From **30 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 Tehran University of Medical Sciences

Street address

Room 105 , 5th floor, Central construction of Tehran University of Medical Sciences, Ghods intersection, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-04-20, 1401/01/31

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.05

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, immediately after that, 2 weeks, and 3 months later

Method of measurement

5-point photonumeric Allergan scale

Secondary outcomes

1

Description

Depth, area and volume of nasolabial folds

Timepoint

Before the intervention, immediately after that, 2 weeks, and 3 months later

Method of measurement

Visioface camera

Intervention groups

1

Description

Injection of Inovo Sense Smile and Inovo Sense Style Intradermal gel in the nasolabial folds, the products are in the 1 ml prefilled sterilized syringe containing: Inovo Sense Smile:Hyaluronic Acid gel 20 mg; Lidocaine hydrochloride, 0.3% ; Phosphate buffer (pH 7), 1 mlInovo Sense Style:Hyaluronic Acid gel, 23 mg; Lidocaine

hydrochloride, 0.3% ; Phosphate buffer (pH 7), 1 ml

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic of Razi Hospital

Full name of responsible person

Amirhooshang Ehsani

Street address

Razi Hospital- Vahdate-e-eslami St, Tehran, Iran

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11996 63911

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ehsanih@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khosro Medisa Teb Company

Full name of responsible person

Masoud Saghafi

Street address

Number 21, Jooybar Alley, Shad St, Molla Sadra St, Tehran, Iran

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Email

contact@kmtmed.com

Web page address

https://www.kmtmed.com/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khosro Medisa Teb 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

Zeynab Aryanian

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Amirhooshang Ehsani

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
Khosro Medisa Teb

Full name of responsible person
Melika Ansari

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
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available