

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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 photonic 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 ml Inovo 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 Saghaei

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**Name of organization / entity**

Tehran University of Medical Sciences

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