Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of efficacy and safety of "MediVim" HA dermal fillers in correction of moderate-to-severe Nasolabial folds

Protocol summary

Study aim

Evaluation of efficacy and safety of "MediVim" HA dermal fillers in correction of moderate-to-severe Nasolabial folds

Design

An interventional, randomized, non-placebo, non-blinded, treatment-intent, single-study, phase 2 clinical trial on 33 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 & 4, one injection with 1 ml of Medivim Filler (produced by Nik Sina Eksir) 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

Medivim Intradermal filler injection in the form of sterilized pre-filled syringes with a volume of 1 ml for 33 patients who have moderate to severe nasolabial folds. Medivim Filler contains: Hyaluronic Acid gel 24 mg; Phosphate buffer (pH 7); Lidocaine hydrochloride, 0.3%

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: **IRCT20220723055530N3**
Registration date: **2024-01-06, 1402/10/16**
Registration timing: **prospective**

Last update: **2024-01-06, 1402/10/16**
Update count: **0**

Registration date

2024-01-06, 1402/10/16

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

2024-01-07, 1402/10/17

Expected recruitment end date

2024-01-14, 1402/10/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy and safety of "MediVim" HA dermal fillers in correction of moderate-to-severe Nasolabial folds

Public title
Assessment of the Results of Medivim 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: **33**
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
2023-12-26, 1402/10/05
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.525

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
Five-point photonumeric Allergan scale

Secondary outcomes

1

Description
Area, depth, 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
Intervention group: Injection of Medivim Intradermal filler in the nasolabial folds, the products are in the 1 ml pre-filled sterilized syringe containing:Medivim:Hyaluronic Acid gel 24 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, Vahdateeslami St, Tehran, Iran
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ehsanih@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nik Sina Eksir
Full name of responsible person
Seyed Mohammad Hosseini
Street address
unit 20, fifth floor, No. 1, Laplace Building, Mosfa (Yas) dead end corner, Safarzadeh St. (Fath), Kaveh Blvd (south), Sadr Highway (west-east route)
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۱۹۳۹۷۵۳۱۶۵
Phone
+98 21 2261 1726
Email
info@ncexir.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nik Sina Eksir
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
Maryam Nasimi
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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