

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 photonic 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 photonic 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 photometric 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  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1199663911  
**Phone**  
+98 21 5563 0705  
**Email**  
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)  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۹۳۹۷۵۳۱۴۰  
**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  
**Street address**  
Razi hospital, Vahdat Eslami Square, Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1199663911  
**Phone**  
+98 21 5563 0705  
**Email**  
nsm.maryam@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Amirhooshang Ehsani  
**Position**  
Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
Razi hospital, Vahdat Eslami Square, Tehran, Iran  
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**Email**  
ehsanih@tums.ac.ir

## Person responsible for updating data

#### Contact

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Tehran University of Medical Sciences  
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Maryam Nasimi  
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Associate professor  
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**Postal code**

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**Phone**

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**Email**

nsm.maryam@gmail.com

**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