

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Safety and effectiveness assessment of Nuxiwell gel produced by Amitis Nik Daroo company for nasolabial folds correction

Protocol summary

Study aim

Safety and efficacy assessment of Nuxiwell intradermal injectable gel for correction of moderate to severe nasolabial folds

Design

Phase II, before after clinical study

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 performed on nasolabial folds. One intradermal injection with Nuxiwell will be performed on each nasolabial fold. The assessment will be repeated right after intervention and 2, 12 and 24 weeks later. Subjects' satisfaction and adverse effect will be recorded in each follow up visit.

Participants/Inclusion and exclusion criteria

18 -65 years old men and women, with moderate to severe nasolabial folds, without any cosmetic facial procedures during last 3 months, with no allergy to gram positive bacteria protein, gel ingredients and no auto immune or immune deficiency diseases. No pregnant and lactating

Intervention groups

one injection with 1-2 cc Nuxiwell injectable gel in each nasolabial fold. The product is 1cc prefilled sterilized syringe containing: 25 mg cross-linked Hyaluronic Acid gel (Odorless, colorless and high concentration, free of fever-causing substances and of non-animal origin) and Phosphate buffer saline.

Main outcome variables

Severity of nasolabial folds according to Allergan grading

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150101020514N16**

Registration date: **2022-10-02, 1401/07/10**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-02, 1401/07/10**

Update count: **0**

Registration date

2022-10-02, 1401/07/10

Registrant information

Name

Alireza Firooz

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 8190

Email address

firozali@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and effectiveness assessment of Nuxiwell gel produced by Amitis Nik Daroo company for nasolabial folds correction

Public title

Safety and effectiveness assessment of Nuxiwell gel produced for nasolabial folds correction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 -65 years old men and women Moderate to severe nasolabial folds based on Allergan criteria The opportunity to accompany the visit programs and study process. Signing the informed consent form and agree to a 6-month follow-up

Exclusion criteria:

Previous hyaluronic acid (HA)-based dermal filler treatment(s) injected within the last 12 months prior to enrollment Cosmetic facial procedures (chemical peel, laser, radio frequency, dermabrasion, ablative or non-ablative procedures), Botox) in the lower 2/3 of the face, within 3 month prior to study entry Planning to undergo any of these procedures at any time during the study

Age

From **18 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 The Institute of Pharmaceutical Sciences of Tehran University of Medical Science

Street address

Unit 1-219, 2nd floor, The Institute of Pharmaceutical Sciences, Faculty of Pharmacy, 16 Azar Avenue

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2022-09-10, 1401/06/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.433

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 and right after intervention and 2, 12 and 24 weeks later

Method of measurement

5 scale Allergan photonic grading

Secondary outcomes

1

Description

Depth, area and volume of nasolabial fold

Timepoint

Before intervention and right after intervention and 2, 12 and 24 weeks later

Method of measurement

Visioface camera

2

Description

Thickness and density of dermis

Timepoint

Before intervention and right after intervention and 2, 12 and 24 weeks later

Method of measurement

Skin ultrasound

Intervention groups

1

Description

Intervention group: one injection with 1-2 cc Nuxiwell injectable gel in each nasolabial fold. The product is 1cc prefilled sterilized syringe containing: 25 mg cross-linked Hyaluronic Acid gel (Odorless, colorless and high concentration, free of fever-causing substances and of non-animal origin) and Phosphate buffer saline.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for research and training in skin diseases and leprosy, Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Street address

415, Taleghani Avenue.

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Fax

Email

dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Amitis Nik Darou co.

Full name of responsible person

Samira Mirzaei

Street address

Unit 37, No. 8, 1st dead end, Sanjabi St., Mader Square, Mirdamad.

City

Tehran

Province

Tehran

Postal code

1911933455

Phone

+98 21 2290 9054

Fax

Email

Amitisnikdarou@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Amitis Nik Darou co.

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

MD and Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

Street address

No. 415, Taleqani Ave.

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Fax

+98 21 8897 2220

Email

dermalab@tums.ac.ir

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

Street address

خیابان طالقانی، شماره 415

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Fax

+98 21 8897 2220

Email

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Dermatology

Street address

No 415, Taleqani St.

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Fax

+98 21 8897 2220

Email

dermalab@tums.ac.ir

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