

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of safety, efficacy and durability of PDO thread lift- EVE & NU series (product of Meditronic Dongjun CO) for facial rejuvenation: An open label, phase 2, before- after, clinical trial.

Protocol summary

Summary

Purpose of the study is the evaluation of safety, efficacy and durability of PDO thread lift- EVE & NU series for facial rejuvenation and face lift. It's an open label, single group, phase 2, before- after, clinical study conducted on 20 male and female subjects 30-60 years old willing to lift the face or eyebrow or improve the nasolabial folds. The intervention will be performed in single session by a trained physician after preb and drep and local anesthesia with lidocaine. Follow up visits will be 3 and 7 days after intervention as well as 1, 3 and 6 months later. Primary endpoint will be improvement assessment by independent dermatologist, based on photographs of the treated area, using the Physician's global assessment score as a reference, at baseline, right after treatment, 1, 3, and 6 months after the treatment. Secondary end points will be Wrinkle analysis done by Visioface 6 months after the treatment and measurement of skin biophysical parameters at month 6.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120720514N6**

Registration date: **2017-11-11, 1396/08/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-11, 1396/08/20

Registrant information

Name

Alireza Firooz

Name of organization / entity

Tehran University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Aftab Forouzan Arya company

Expected recruitment start date

2017-07-04, 1396/04/13

Expected recruitment end date

2017-08-04, 1396/05/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety, efficacy and durability of PDO thread lift- EVE & NU series (product of Meditronic Dongjun CO) for facial rejuvenation: An open label, phase 2, before- after, clinical trial.

Public title

Evaluation of safety and efficacy of two types of thread lift for facial rejuvenation.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male and female subjects 30-60 years old; willing to lift the face or eyebrow or improvement the nasolabial folds; providing written informed consent and attendance in follow up session. Exclusion criteria:

History of any rejuvenated procedure during last years in face area; history of any Botulinum, laser, or intense pulsed light during last 6 month; history of Isotretinoin during last 3 month; collagen vascular disease; any systemic or topical disorders which interfere with process of wound healing; history of any implant in face area; severe cardiac disease or cardiac pacemaker; any active, chronic and recurrent infection; bleeding disorders, coagulopathy, any drugs affect bleeding time; susceptibility to keloids or scar formation; active smoker (last 2 years); pregnancy/ breast feeding

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

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

Tehran University of Medical Science

Street address

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

City

Tehran

Postal code

1417653761

Approval date

2017-05-14, 1396/02/24

Ethics committee reference number

IR.TUMS.VCR.REC.1396.2293

Health conditions studied

1

Description of health condition studied

skin rejuvenation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

improvement assessment using the Physician's global assessment score

Timepoint

before and 1,3,6 months after treatment

Method of measurement

based on pictures

Secondary outcomes

1

Description

skin hydration

Timepoint

before and after 1,3,6 months

Method of measurement

Corneometer® - Courage - Khazaka

2

Description

Trans epidermal water loss

Timepoint

before and after 1,3,6 months

Method of measurement

Tewameter® TM 300 - Courage - Khazaka

3

Description

depth, area and volume of wrinkle in intervention area

Timepoint

before and after 1,3,6 months

Method of measurement

VisioFace

Intervention groups

1

Description

single session inserting treated lift by a trained physician after preb and drep and local anesthesia with lidocaine

Category

Treatment - Surgery

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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Aftab Froozan Arya Organization

Full name of responsible person

Fariba Paslar

Street address

No 42, Nahid Alley, Mirzaye Shirazi St., Motahari St.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Aftab Froozan Arya Organization

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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

Full name of responsible person

Aniseh Samadi

Position

MD and Researcher

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Alireza Firooz

Position

Dermatologist and professor of Tehran University of Medical Sciences.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Aniseh Samadi

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty