

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of effect of micro-needling on perioral wrinkles

Protocol summary

Study aim

Evaluation of the effect of micro-needling on perioral wrinkle

Design

single-armed clinical trial, nonblinded, phase 2 on 30 patients

Settings and conduct

This project is done in the dermatology clinic of saint Alzahra hospital of Isfahan. Micro-needling is done on perioral wrinkles. Patients are treated with 3 sessions of micro-needling 2 weeks apart, wrinkles around the mouth are photographed before the start of treatment, 6 weeks later and 3 months after the last session, photography is done with the same condition at a distance of 30 cm.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Females over the age of 40 Skin types 1, 2 and 3 Exclusion criteria: Sensitivity to metal The presence of coagulation disease or the use of anticoagulants Dermatitis or infection of the study area Use of Botox during the last 6 months Using other methods of removing wrinkles in the last 3 months Scarring and skin disease in the study area Tobacco use

Intervention groups

Patients are treated with 3 sessions of micro-needling 2 weeks apart, wrinkles around the mouth are photographed before the start of treatment, 6 weeks later and 3 months after the last session, photography is done with the same condition at a distance of 30 cm.

Main outcome variables

The degree of improvement of wrinkles from the patient's point of view; The degree of improvement of wrinkles from the expert's point of view

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211028052900N1**

Registration date: **2022-01-01, 1400/10/11**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-01, 1400/10/11**

Update count: **0**

Registration date

2022-01-01, 1400/10/11

Registrant information

Name

Maryam Fatahinasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3626 3176

Email address

rezamdmr70@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of micro-needling on perioral wrinkles

Public title

Evaluation of effect of micro-needling on perioral wrinkles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Females older than 40years old Skin types of 1,2 and 3

Exclusion criteria:

Existing scar or other dermatologic disease in perioral area tobacco use Using other methods of perioral wrinkle elimination in past 3 months Botox injection in past 6 months Sensitivity to metal The presence of coagulation disorder or the use of anticoagulants

Age

From **40 years** old

Gender

Female

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 Isfahan University of Medical Sciences

Street address

No. 43, rsashtchi alley, mohtasham kashani ave.

City

Isfahan

Province

Isfahan

Postal code

8175915438

Approval date

2021-11-28, 1400/09/07

Ethics committee reference number

ir.mui.med.rec.1400.438

Health conditions studied

1

Description of health condition studied

perioral wrinkle

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The degree of improvement of wrinkles from the patient's point of view

Timepoint

prior to intervention, 6 weeks later and 3 month after last session

Method of measurement

Visual Analogue Scale

2

Description

The degree of improvement of wrinkles from the expert's point of view

Timepoint

prior to intervention, 6 weeks later and 3 month after last session

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 3 sessions of microneedling 2 weeks apart, digital camera photography (canon power shot S95), inopen microneedling device made in USA and needle depth between 1.5 to 2 mm

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Maryam Fattahinasab

Street address

Soffe blvd.

City

Isfahan

Province

Isfahan

Postal code

81746 75731

Phone

+98 31 3620 2020

Email

alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansoor Siavash

Street address

Hezar harib Ave

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 5149

Email

research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Fattahinasab

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No 43. Rashtchi alley, mohtasham kashani Ave

City

Isfahan

Province

Isfahan

Postal code

8175915483

Phone

+98 31 3626 3176

Email

rezamdmr70@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Fattahinasab

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No 43, rashtchi alley, mohtasham kashani ve

City

Isfahan

Province

Isfahan

Postal code

8175915483

Phone

+98 31 3626 3176

Email

rezamdmr70@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Fattahinasab

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No 43, rashtchi alley, mohtasham kashani Ave

City

Isfahan

Province

Isfahan

Postal code

8175915438

Phone

0098031036263176

Email

rezamdmr70@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be published after being unidentifiable.

When the data will become available and for how long

Start access 1 month after publishing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of data in scientific studies and review studies can be used by mentioning the source. Statistical analysis is permitted with the prior permission of researchers.

From where data/document is obtainable

To use the documents and get permission, call rezamdmr70@yahoo.com or phone number 0989396845002. Dr. Maryam Fattahi Nasab Isfahan Al-Zahra Hospital Dermatology Clinic

What processes are involved for a request to access data/document

After sending an email or making a call, the unidentifiable documents will be sent to the requesting person by email within a month.

Comments