

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the safety and effectiveness of liposomal formulation of placenta extract after microneedling in the treatment of skin aging

Protocol summary

Study aim

Evaluation of the safety and effectiveness of liposomal formulation of placenta extract after microneedling in the treatment of skin aging

Design

Clinical trial with control and intervention groups, parallel groups, single-blind, non-randomized, phase 1-2

Settings and conduct

To evaluate this product, patients receiving laser for skin aging treatment at the Skin and Stem Cell Research Center of Tehran University of Medical Sciences will be evaluated. The product will be evaluated topically in both lyophilized and liposomal lyophilized forms. Patients will undergo clinical evaluations and the restored range will be evaluated. Patients are not aware of the type of liposomal or non-liposomal product.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 20 and 60 years old, having moderate wrinkles in each area of the face.
Exclusion criteria: pregnant or lactating patients, cancer history, patients with a recent history of gel and botox injection, people with mental disorders, active infection in the face area

Intervention groups

Control group: the patient receives the non-liposomal product immediately after microneedling in three sessions with an interval of one month. Intervention group: the patient receives the liposomal product immediately after microneedling in three sessions with an interval of one month.

Main outcome variables

The amount of wrinkles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N23**

Registration date: **2023-02-05, 1401/11/16**

Registration timing: **prospective**

Last update: **2023-02-05, 1401/11/16**

Update count: **0**

Registration date

2023-02-05, 1401/11/16

Registrant information

Name

Sona Zare

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2665 7438

Email address

sonazarebio@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the safety and effectiveness of liposomal formulation of placenta extract after microneedling in the treatment of skin aging

Public title

Evaluation of liposomal formulation of placenta extract after microneedling in the treatment of skin aging

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 20-60 Having middle wrinkles in face region

Exclusion criteria:

Pregnancy and breastfeeding History of cancer Patients with a new history of gel and Botox injections People with Mental Disorders Active infection in the face

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Patients are given a general explanation about the intervention methods, but one method is not introduced as superior to the other method and no preference is given to one of the interventions, so patients are blind to the effect of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Organizational committee of ethics in biomedical research Shahid Beheshti University of Medical Scie

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi Ave, Yaman Ave, Velenjak

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2022-09-11, 1401/06/20

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.369

Health conditions studied**1****Description of health condition studied**

skin aging

ICD-10 code

L90.9

ICD-10 code description

Atrophic disorder of skin

Primary outcomes**1****Description**

The amount of wrinkles

Timepoint

Before treatment and six month after the last session

Method of measurement

Visio face

Secondary outcomes**1****Description**

Inflammation

Timepoint

After each session

Method of measurement

Questionnaire and visit

2**Description**

Intensity of pain

Timepoint

Treatment time

Method of measurement

Questionnaire and visit

Intervention groups**1****Description**

Control group: the patient receives the non-liposomal product immediately after microneedling in three sessions with an interval of one month.

Category

Treatment - Other

2

Description

Intervention group: the patient receives the liposomal product immediately after microneedling in three sessions with an interval of one month.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin and Stem Cell Research Center Clinic of the University of Science Tehran Medicine

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Street address

No 4, Maryam Alley, South Kamraniyeh Street

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1937957511

Phone

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Email

Dr_nilforoush@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sadi Banar

Street address

Laser Application in Medical Sciences Research Center, Shohadaye-Tajrish Educational Hospital, Tajrish Sq, Tehran, Iran

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1989934370

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+98 21 2271 8021

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laser.cntr@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Skin and stem Cell Research Center, Tehran University of Medical Sciences

Full name of responsible person

Sona Zare

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Cellular and Molecular Biology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Professor

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Subspecialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

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Other areas of specialty/work

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable