

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of safety and effectiveness of liposomal formulations of amniotic membrane in treatment skin aging after laser rejuvenation (phase I / II clinical trial)

Protocol summary

Study aim

Evaluation of safety and effectiveness of liposomal formulations of amniotic membrane in treatment of skin aging after laser rejuvenation (phase I / II clinical trial)

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 20-60; Having moderate wrinkles on the face. Exclusion criteria: Pregnancy and breastfeeding; Active infection in face; Using any injectable fillers on the face in the last six months

Intervention groups

Control group: 10 The patient uses the non-liposomal product immediately after laser rejuvenation in three sessions with an interval of one month. Intervention group: 10 The patient uses the liposomal product immediately after laser rejuvenation 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: **IRCT20200127046282N25**

Registration date: **2023-02-18, 1401/11/29**

Registration timing: **prospective**

Last update: **2023-02-18, 1401/11/29**

Update count: **0**

Registration date

2023-02-18, 1401/11/29

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

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and effectiveness of liposomal formulations of amniotic membrane in treatment skin

aging after laser rejuvenation (phase I / II clinical trial)

Public title

Evaluation of liposomal formulations of amniotic membrane in treatment skin aging after laser rejuvenation

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
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The data analyst will be blinded and will not know the control and treatment groups. The patient will not be aware of being in the control and test groups, and the product of each group will be used in the same form.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz blvd

City

Tehran

Province

Tehran

Postal code

1937957511

Approval date

2022-10-10, 1401/07/18

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.539

Health conditions studied

1

Description of health condition studied

skin aging

ICD-10 code

L90.9

ICD-10 code description

Atrophic disorder of skin, unspecified

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 of treatment

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: 10 patients use Amnion's non-liposomal product (Zist Sakht Bonyan Pars company) topically immediately after fractional CO2 laser rejuvenation in three sessions with an interval of one month.

Category

Treatment - Other

2

Description

Intervention group: 10 patients use amnion liposomal product (Zist Sakht Bonyan Pars company) topically immediately after fractional CO2 laser rejuvenation 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

City

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Postal code

1937957511

Phone

+98 21 2665 7438

Email

Dr_nilforoush@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fatuhi

Street address

Floor 6th vice president of research and technology, Corner of Qods St., Central University Organization, Keshavarz Blvd.

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+98 21 8163 3698

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ir.ac.tums@vcr

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

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

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

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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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Postal code

1937957511

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

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

Analytic Code

Not applicable

Data Dictionary

Not applicable