Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Efficacy and safety of non-cross-linked hyaluronic acid containing exosomes derived from fibroblast cells foreskin in rejuvenating the skin around the eyes in humans (clinical trial phase 1 & 2)

Protocol summary

Study aim

The main purpose of the study is specifically to investigate the effect of non-cross-linked hyaluronic acid containing exosomes derived from fibroblast cells foreskin in rejuvenating the skin around the eyes in humans. Evaluating the effectiveness of exosomes derived from foreskin fibroblasts to improve the thickness of the skin around the eyes Determining the optimal dose of exosomes derived from foreskin fibroblasts on increasing the proliferation of human fibroblast cells and the production and secretion of collagen and increasing angiogenesis for collagen synthesis. Safety evaluation of exosomes derived from foreskin fibroblasts for use in humans

Design

This phase 1 and 2 clinical trial study is conducted in the form of simple randomization and double-blind, on 21 patients in 3 groups.

Settings and conduct

Intradermal injection (5 to 15 mm), 5 entry points, Skin and Stem Cell Research Center, Tehran University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria : The age of these people to enter the study is between 35 and 45 years old. The skin around the eyes (crow's feet area) of patients has lost its original properties and started to wrinkle. Non-entry criteria: Allergy to injections and syringes People who participate in this study should not have used rejuvenation methods such as Botox 4 to 6 months before the start of the study and injections. Hypersensitivity to non-crosslinked hyaluronic acid

Intervention groups

Dividing patients into 3 groups: Group a: receiving a dose of 50 µg of exosomes Group b: receiving a dose of 100 µg of exosomes Group c: receiving a dose of 200 µg of exosomes

Main outcome variables

Treatment complications, recovery rate, recovery time , patient satisfaction, skin collagen level, epidermis and dermis thickness, skin brightness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221130056672N5**
Registration date: **2024-01-29, 1402/11/09**
Registration timing: **prospective**

Last update: **2024-01-29, 1402/11/09**
Update count: **0**

Registration date

2024-01-29, 1402/11/09

Registrant information

Name

EHSAN Taghiabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2665 7541

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-25, 1403/01/06

Expected recruitment end date

2024-05-04, 1403/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of non-cross-linked hyaluronic acid containing exosomes derived from fibroblast cells foreskin in rejuvenating the skin around the eyes in humans (clinical trial phase 1 & 2)

Public title

Efficacy and safety of non-cross-linked hyaluronic acid containing exosomes derived from fibroblast cells foreskin in rejuvenating the skin around the eyes in humans

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The age of these people to enter the study is between 35 and 45 years old. The skin around the eyes (crow's feet area) of patients has lost its original properties and started to wrinkle.

Exclusion criteria:

Allergy to injections and syringes People who participate in this study should not have used rejuvenation methods such as Botox 4 to 6 months before the start of the study and injections. Hypersensitivity to non-crosslinked hyaluronic acid

Age

From **35 years** old to **45 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **21**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a simple randomization method, patients who visit the skin clinic of Dr. Nilfroshzadeh are divided into 3 groups, so that one envelope is randomly selected for each patient from the number of 21 sealed envelopes. Each envelope contains the letters a, b, or c. Group a patients are treated with a concentration of 50 micrograms, group b with a concentration of 100 micrograms, and group C patients with a concentration of 200 micrograms.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participant researcher, physician and evaluating physician will be unaware of the type of treatment until the end of the study.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

research ethics committees of research institute for Oncology, Hematology and cell therapy - Tehran

Street address

13th Floor, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Simai Iran Street, Quds Town (West), Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2023-12-13, 1402/09/22

Ethics committee reference number

IR.TUMS.HORCSCT.REC.1402.054

Health conditions studied

1

Description of health condition studied

skin rejuvenation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Rejuvenation of crow's feet skin around the eyes

Timepoint

Changes in the mentioned area are measured 4 weeks, 8 weeks, and 12 weeks after the injection, and 8 weeks after the last injection (20 weeks from the day of injection), final examinations are performed.

Method of measurement

1- Visio face: a full-face photography method for facial skin analysis, optimal product recommendation and treatment documentation. Using this method, before and after the skin and the surface and depth of wrinkles are measured. 2- Colorimeter: The colorimeter contains a photocell that is able to detect the amount of light passing through the investigated solution. As a result, the color is checked before and after the end of the test

so that a diagnosis can be made in case of lightening of the skin. 4- Sonography: This test is also used to measure thickness and density.

Secondary outcomes

1

Description
Safety
Timepoint
Checks for safety are done one week after each injection and before the time of re-injection.
Method of measurement
Patient history and lack of swelling in the injection area

Intervention groups

1

Description
Group a: treated with non-cross-linked hyaluronic acid combination (0.5 cc) along with exosomes derived from fibroblast foreskin at a dose of 50 micrograms
Category
Treatment - Other

2

Description
Group b: Treated with a combination of non-cross-linked hyaluronic acid (0.5 cc) along with exosomes derived from fibroblast foreskin with a dose of 100 micrograms.
Category
Treatment - Other

3

Description
Group c: treated with non-cross-linked hyaluronic acid combination (0.5 cc) along with exosomes derived from fibroblast foreskin with a dose of 200 micrograms
Category
Treatment - Other

4

Description
Control group: Treated with 0.5cc of non-cross-linked hyaluronic acid
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Skin and Stem Cell Research Center, Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Nilfrooshzadeh
Street address
No.4 Maryam Dead End South Kamraniyeh, Andarzgo Blv, Tehran Province, Tehran
City
Tehran
Province
Tehran
Postal code
1937957511
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+98 21 2665 7541
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etaghiabadi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Vice President of Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Nilfroushzadeh
Street address
Research and Technology Deputy, 6th floor , Quds St, Tehran University of Medical Sciences
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Email
etaghiabadi@sina.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Vice President of 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
Ehsan Taghiabadi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Applied cell sciences

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Associate professor

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Person responsible for updating data

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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 shared after de-identifying individuals.

When the data will become available and for how long
Six months after the publication and printing of the article

To whom data/document is available
Academic researchers and experts

Under which criteria data/document could be used
In order to analyze the results of the study outcomes

From where data/document is obtainable
etaghiabadi@sina.tums.ac.ir

What processes are involved for a request to access data/document
It can be submitted after review by the Research Council of the Skin and Stem Cell Research Center of Tehran University of Medical Sciences, which usually takes 2 to 3 months.

Comments