

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Safety and efficacy assessment of adipose-derived mesenchymal stem cell conditioned media in combination with crosslinked-hyaluronic acid for skin rejuvenation: an in vitro and clinical study (phase I & II)

Protocol summary

Study aim

Enrichment of the optimal percentage of HA using the optimal percentage of culture medium derived from ADSC with the aim of increasing the continuity of the rejuvenation method with injectable fillers

Design

Parallel group trial contain control group, single blind, design for 35 candidate in phase 1 and 2 clinical trial

Settings and conduct

The study aims to enrich the HA by using the culture medium derived from ADSC with the aim of investigating the continuity of the rejuvenation with injectable fillers, in a blinded design, the main researcher knows which kind of treatment was given to the participants. Volunteers receives HA along with supernatant on one side of the face in the smile line area and HA alone on the other side.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male and female aged about 35 to 65 years old, having no anatomic disorder in the face, the candidate with moderate wrinkles according to Glogue scale 2-4. Exclusion criteria: Heavy smokers or drinkers, applying skin rejuvenation intervention in the face in the past 6 months or during the study, a candidate with wrinkles according to a Glogue scale 1 and 5, the candidate with a history of related skin diseases

Intervention groups

The intervention group receives 1cc of HA in combination with the supernatant of ADSC on one side of the smile line for candidates between the ages of 35 and 65. The study runs in parallel and the candidate receives hyaluronic acid alone on the other side of the face.

Main outcome variables

Change in melanin production; change in skin elasticity; Change in skin wrinkle; durability of HA at the injection site

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230324057772N2**

Registration date: **2024-02-13, 1402/11/24**

Registration timing: **prospective**

Last update: **2024-02-13, 1402/11/24**

Update count: **0**

Registration date

2024-02-13, 1402/11/24

Registrant information

Name

Mahsa Mollapour Sisakht

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4462 0324

Email address

mahsamollapour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-14, 1403/02/25

Expected recruitment end date

2024-11-15, 1403/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy assessment of adipose-derived mesenchymal stem cell conditioned media in combination with crosslinked-hyaluronic acid for skin rejuvenation: an in vitro and clinical study (phase I & II)

Public title

Adipose-derived mesenchymal stem cell conditioned media in combination with crosslinked-hyaluronic acid for skin rejuvenation

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Male and female, age about 35 to 65 years old Having no anatomic disorder in face Candidate with mild to moderate wrinkles according to Glogue scale 2-4 Normal mental health based on the self assesment Having a good cooperation with research team

Exclusion criteria:

Heavy smokers or drinkers Applying skin rejuvenation intervention in face at past 6 months or during the study Having a mental disorder based on the self assesment Candidate with wrinkles according to Glogue scale 1 and 5 Having an obsessed disorder Having any related skin disorder

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, this method is equivalent to tossing a coin for each subject that enters a trial, such as Heads = Active, Tails = Placebo. Implementation and treatment of assignments are completely unpredictable.

Blinding (investigator's opinion)

Single blinded

Blinding description

Only the researcher doing the study knows which group received fat-derived mesenchymal stem cell supernatant in combination with crossed-link HA treatment or only crossed-link HA until the trial is over.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine- Tehran University of Medical Sciences

Street address

6th floor, Qods Ave., Keshavarz Blvd., Tehran University of Medical Sciences, Central building

City

Tehran

Province

Tehran

Postal code

1417755354

Approval date

2023-12-13, 1402/09/22

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.503

Health conditions studied

1

Description of health condition studied

rejuvenation

ICD-10 code

L98.8

ICD-10 code description

Other specified disorders of the skin and subcutaneous tissue

Primary outcomes

1

Description

Quantity of nasolabial fold wrinkle - Extension

Timepoint

Before the injection and after 1 and 3 months

Method of measurement

Biometry with visioface & skin sonography

2

Description

Quality of nasolabial fold wrinkle - deep

Timepoint

Before the injection and after 1 and 3 months

Method of measurement

Visio face and skin sonography

Secondary outcomes

1

Description

Skin elasticity

Timepoint

Before the intervention, 1 and 3 months
Method of measurement
Skin sonography

2

Description

Melanin level in skin

Timepoint

Before the intervention, 1 and 3 months

Method of measurement

Biometry with colorimeter

Intervention groups

1

Description

Intervention group: The group who receive 3% of HA and supernatant of ADSC, one time, subdermal injection at one side of the face in the laugh line

Category

Treatment - Other

2

Description

Control group: group who receive HA alone, one time, at one side and the laugh line, biometric assessment after one month

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin and stem cell research cenetr, Tehran University of Medical Sciences

Full name of responsible person

Mahsa Mollapour

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No.4, Maryam Dead End, South Andarzgo Blvd., Kamraniyeh Ave., Tehran, Iran

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mahsamollapour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Street address

No.4, Maryam Dead End, South Andarzgo Blvd., Kamraniyeh Ave., Tehran, Iran

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Dr_nilforoush@yahoo.com

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

Mahsa Mollapour

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahsa Mollapour

Position

Assistant professor

Latest degree

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Other areas of specialty/work

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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 is potentially shareable after de-identifying individuals

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Only available for people working in academic institutions

Under which criteria data/document could be used

The use and analysis of data is not allowed without the permission of the principal investigator

From where data/document is obtainable

Information will be send after receiving email request by principal investigator

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

After receiving the email, the information will be provided to the qualified applicant within a maximum period of one month

Comments

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahsa Mollapour

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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