Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 contian 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 rejuvination 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 elastisity

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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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
Street address
No.4, Maryam Dead End, South Andarzgo Blvd., Kamraniyeh Ave., Tehran, Iran
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Assistant professor

Latest degree
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Other areas of specialty/work
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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 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