Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation the safety and efficacy of decellularized umbilical cord extracellular matrix (ECM) derived hydrogel in the treatment of skin wrinkles

Protocol summary

Study aim

Phase I: Investigating the safety and feasibility of combined microneedling treatment with hydrogel derived from decellularized umbilical cord ECM to facial skin to reduce the effects of aging and rejuvenation.
Phase II: Investigating the effectiveness of combining microneedling combined treatment with hydrogel derived from decellularized umbilical cord ECM to facial skin to reduce the effects of aging and rejuvenation compared to the placebo group

Design

The clinical trial has a control group, with a parallel group, double-blind, randomized, phase one and two on 20 patients, and the patients will be randomized through the online method of sealedenvelope.com as a combination of blocks 4 and 2.

Settings and conduct

In this study, 20 patients referred to the skin clinic who meet the entry criteria and do not have the exit criteria are examined.In case of Willingness to participate in the study, the consent form will be signed by the patient, and then general and specific questionnaires according to the goals of the project will be completed.

Participants/Inclusion and exclusion criteria

age 35-65 Wrinkle lines on the face should be in the range of 3-5 based on the Wrinkle severity rating scale.

Intervention groups

20 patients are tested in two groups. 10 patients are in the group receiving hydrogel and 10 patients are in the group receiving placebo (normal saline).

Main outcome variables

Absence of side effects, including short-term and long-term, systemic or local side effects, and severe or mild side effects in the treatment with hydrogel derived from decellularized umbilical cord ECM (zero and 2 weeks, 1, 2, 4 and 6 months after first injection) through clinical examination and review CTCAE v5

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210612051545N2**
Registration date: **2022-09-10, 1401/06/19**
Registration timing: **prospective**

Last update: **2022-09-10, 1401/06/19**
Update count: **0**

Registration date

2022-09-10, 1401/06/19

Registrant information

Name

Amir Bajouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2221 2537

Email address

bajouri.md@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation the safety and efficacy of decellularized umbilical cord extracellular matrix (ECM) derived hydrogel in the treatment of skin wrinkles

Public title
hydrogel effectiveness in the treatment of skin wrinkles

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Wrinkle lines on the face should be in the range of 3-5 based on Wrinkle Severity Rating Scale

Exclusion criteria:
Suffering from uncontrolled chronic diseases including diabetes mellitus, underlying chronic liver, kidney and heart disease, chronic malnutrition, malignancy, coagulopathy or the use of anticoagulants, a history of autoimmune diseases and suffering from HBV, HIV, HCV viral infections Any cosmetic procedure such as fat injection within a year and permanent filler, microneedling, RF, laser and other cases within the last 6 months, except for using cream. Infection and any malignancy at the transplant recipient site Failure to receive cells in the treatment area during the past year Patients with vitiligo Moderate to severe chronic skin diseases such as eczema and psoriasis active acne People who have had systemic retinoid treatment (within the last 6 months) or topical retinoid treatment (within the last 2 weeks) History of keloid Women during pregnancy and breastfeeding Patients undergoing radiotherapy and chemotherapy

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

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: simple; Randomization unit: individual; randomization does not have a layer. Randomization tool: table of random numbers. Concealment: Cellular and non-cellular product is delivered to the doctor in the form of a code and given to the patient based on the randomization table.

Blinding (investigator's opinion)
Double blinded

Blinding description
Randomization master sheet Based on the random sequence of anonymous 4-digit codes, they are generated on the sealedenvelope.com website and attached to the products as labels. In the same way, it is sent to the study site. The randomization table is strictly confidential and will only be available to the clean room manager. Patients, as well as doctors and statisticians, will not know the type of treatment received. In CRF (Case Report Form) of patients 4 digits of the product code and 4 digits of the code are registered with the first two letters of the patient's name and surname. The 8-digit codes are transferred to the data bank, and then the list of 8-digit codes in the two groups receiving cells and placebo is given to the data management team in a blinded form in columns A and B. Also, the results of additional paraclinical studies The treating physician will be evaluated by another specialist physician who is not aware of the treatment process.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Tehran Province, Tehran, No 4 Maryam Dead End South Andarzgo Blvd، Kamraniyeh

City
Tehran

Province
Tehran

Postal code
1937957511

Approval date
2022-08-30, 1401/06/08

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.418

Health conditions studied

1

Description of health condition studied
skin wrinkles

ICD-10 code
L98.8

ICD-10 code description
Other specified disorders of the skin and subcutaneous tissue

Primary outcomes

1

Description
Absence of side effects, including short-term and long-

term, systemic or local side effects, and severe or mild side effects in the treatment with hydrogel derived from decellularized umbilical cord ECM (zero and 2 weeks, 1, 2, 4 and 6 months after first injection) through clinical examination and CTCAE v5 review

Timepoint

(zero and 2 weeks, 1, 2, 4 and 6 months after first injection

Method of measurement

Wrinkle reduction based on WSRS score reduction six months after injection. Reduction of wrinkles based on the increase in GAIS score two weeks, 1, 4, and 6 months after the first injection)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: local transplantation of hydrogel derived from decellularized extracellular matrix (ECM) of the umbilical cord was designed in 10 candidates with wrinkles. 3 times of hydrogel derived from decellularized extracellular matrix (ECM) at an interval of 2 weeks is injected. Follow-up is done in the 1st and 2nd week and in the 2nd, 4th and 6th months after the injection.

Category

Treatment - Other

2

Description

Control group: In 10 candidates with wrinkles, 3 times of physiologic serum at an interval of 2 weeks is injected. Fallow up is done in the 1st and 2nd week and in the 2nd, 4th, and 6th months after the injection.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin and stem cell research center

Full name of responsible person

Amir Bajoury

Street address

No 4 Maryam Dead End South Andarzgo Blvd، Kamraniyeh

City

Tehran

Province

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1937957511

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Email

bajouri.md@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Amir Amirkhani

Street address

NO 4, Maryam dead end, South kamraniye

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Postal code

1996810005

Phone

+98 21 8805 1376

Email

amirkhani@health.gov.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

ViraCellule Co

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Amir Bajouri

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Medical Biotechnology

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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
Specialist
Other areas of specialty/work
Dermatology
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Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Amir Bajouri
Position
Researcher
Latest degree
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Medical Biotechnology
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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 blinding the individuals
When the data will become available and for how long
6 months after publishing the manuscript
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
In order to analyze the data related to the study outcome
From where data/document is obtainable
Amir bajouri bajouri.md@gmail.com
What processes are involved for a request to access data/document
After reviewing in the Research Council of University of Medical Sciences can be presented which usually takes 1 to 2 months
Comments