

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### evaluation of human placenta extract effectiveness in the treatment of skin wrinkles: A phase I/II clinical trial

#### Protocol summary

##### Study aim

Phase I: Investigating the safety and feasibility of combined microneedling treatment with human placenta extract to facial skin to reduce the effects of aging and rejuvenation. II: Investigating the effectiveness of combining microneedling combined treatment with human placenta extract 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 human placenta extract (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: **IRCT20210612051545N3**

Registration date: **2022-09-20, 1401/06/29**

Registration timing: **prospective**

Last update: **2022-09-20, 1401/06/29**

Update count: **0**

##### Registration date

2022-09-20, 1401/06/29

##### 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 of human placenta extract effectiveness in the treatment of skin wrinkles: A phase I/II clinical trial

**Public title**

human placenta 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

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No 4 Maryam Dead End South Andarzgo Blvd. Kamraniyeh

**City**

Tehran

**Province**

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**Postal code**

1937957511

**Approval date**

2022-08-30, 1401/06/08

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1401.417

**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: 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. Follow 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

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### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Tehran University of Medical Sciences

###### **Full name of responsible person**

Mohammad Amir Amirkhani

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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**

Vira Cellule 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 Bajoury

###### **Position**

Researcher

###### **Latest degree**

Medical doctor

###### **Other areas of specialty/work**

Medical Biotechnology

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## Person responsible for scientific inquiries

### Contact

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Tehran University of Medical Sciences  
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Mohammad Ali Nilforoushzadeh  
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Professor  
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**Other areas of specialty/work**  
Dermatology  
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## Person responsible for updating data

### Contact

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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 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