

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Investigation of the safety and effectiveness of exosome derived from human umbilical cord jelly Wharton mesenchymal stem cells injection compared to intralesional triamcinolone injection in the treatment of alopecia areata: a randomized, blinded clinical trial

#### Protocol summary

##### Study aim

Investigation of the safety and effectiveness of exosome derived from human umbilical cord jelly Wharton mesenchymal stem cells injection compared to intralesional triamcinolone injection in the treatment of alopecia areata: a randomized, blinded clinical trial

##### Design

This study is conducted as a phase 1 study on 20 patients with alopecia areata. In the intervention group, each patient will receive 3 sessions at 4-week intervals, with exosome injections in each session, and in the control group, each patient will receive triamcinolone injections in 3 sessions at 1-month intervals.

##### Settings and conduct

This project is being carried out at the Skin and Stem Cell Research Center of Tehran University of Medical Sciences. The intervention group will receive exosome injections, while the control group will receive triamcinolone injections.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: men and women with alopecia areata, age 18 years and older and less than 50 years, complete patient consent to participate in the project. Exclusion criteria: platelet disorders, thrombocytopenia, patients receiving anticoagulants, patients with malignancy, receiving chemotherapy in the last 5 years, patients with sepsis, smoking, pregnancy, ulcers or active infections at the treatment site.

##### Intervention groups

In the intervention group, patients receive three sessions, one month apart, of intradermal injection of one cc of exosomes at a concentration of 50 micrograms per milliliter in the area with hair loss, and in the control group, patients receive three sessions, one month apart, of intradermal injection of one cc of triamcinolone at a concentration of 2.5-5 mg per milliliter in the area with

hair loss.

##### Main outcome variables

The amount of hair loss; side effects; patient's satisfaction; tolerability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200127046282N65**

Registration date: **2025-12-26, 1404/10/05**

Registration timing: **prospective**

Last update: **2025-12-26, 1404/10/05**

Update count: **0**

##### Registration date

2025-12-26, 1404/10/05

##### Registrant information

##### Name

Sona Zare

##### Name of organization / entity

Skin and Stem Cell Research Center, Tehran  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2665 7438

##### Email address

sonazarebio@gmail.com

##### Recruitment status

**recruiting**

##### Funding source

##### Expected recruitment start date

2026-01-05, 1404/10/15  
**Expected recruitment end date**  
2026-06-20, 1405/03/30  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Investigation of the safety and effectiveness of exosome derived from human umbilical cord jelly Wharton mesenchymal stem cells injection compared to intralesional triamcinolone injection in the treatment of alopecia areata: a randomized, blinded clinical trial

**Public title**  
Study of exosome injection in the treatment of alopecia areata

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Men and women with alopecia areata Age 18 years and older and less than 50 years Complete patient consent to participate in the project

**Exclusion criteria:**

Platelet disorders Thrombocytopenia Patients receiving anticoagulants Patients with malignancy Receiving chemotherapy during the last 5 years Patients with sepsis Being a smoker Pregnancy Active wound or infection at the treatment site Do not receive any topical or systemic medication in the last 3 months Women with hyperprolactinemia Women with hormonal disorders or polycystic ovaries

**Age**

From **18 years** old to **49 years** old

**Gender**

Both

**Phase**

1

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Outcome assessors will be considered blind.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Working Group/Ethics Committee in Research Faculty of Medicine - Tehran University of Medical Scienc

**Street address**

Elkhebal St., Quds St., Porsina St., Faculty of Medicine

**City**

Tehran

**Province**

Tehran

**Postal code**

1461884513

**Approval date**

2025-12-21, 1404/09/30

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1404.578

## Health conditions studied

### 1

**Description of health condition studied**

alopecia areata

**ICD-10 code**

L63.9

**ICD-10 code description**

Alopecia areata, unspecified

## Primary outcomes

### 1

**Description**

The amount of hair loss

**Timepoint**

Before treatment and three month after the last session

**Method of measurement**

Trichoscan

## Secondary outcomes

### 1

**Description**

Side effects

**Timepoint**

One week after session

**Method of measurement**

Standard for pharmacovigilance research group in europe questionnaire and visit

### 2

**Description**

Satisfaction

#### **Timepoint**

Three months after the last session

#### **Method of measurement**

Patient consent questionnaire and visit

### **3**

#### **Description**

Tolerability

#### **Timepoint**

Each session after transplantation

#### **Method of measurement**

Patient tolerance questionnaire and visit

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Patients receive three sessions, one month apart, of intradermal injection of one cc of exosomes at a concentration of 50 micrograms/ml into the area with hair loss.

#### **Category**

Treatment - Other

### **2**

#### **Description**

Control group: Patients receive three sessions, one month apart, of intradermal injection of one cc of triamcinolone at a concentration of 2.5-5 mg/ml into the area with hair loss.

#### **Category**

Treatment - Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Clinic of Skin and Stem cell Research Center of  
Tehran University of Medical Sciences

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

Mohammad Ali Nilforoushzadeh

##### **Street address**

No 4, Maryam Alley, South Kamraniyeh Street

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1937957511

##### **Phone**

+98 21 2665 7438

##### **Email**

Dr\_nilforoush@yahoo.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

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

Tehran University of Medical Sciences

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

Ramin Kordi

##### **Street address**

Vice President for Research and Technology, 6th  
Floor, Central University Organization, corner of Qods  
Street, Keshavarz Boulevard

##### **City**

Tehran

##### **Province**

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##### **Postal code**

141765383761

##### **Phone**

+98 21 8163 3698

##### **Email**

vcr@tums.ac.ir

#### **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**

Skin and Stem cell Research Center of Tehran  
University of Medical Sciences

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

Sona Zare

##### **Position**

Researcher

##### **Latest degree**

Ph.D.

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

Cellular and Molecular biology

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Skin and Stem cell Research Center of Tehran  
University of Medical Sciences  
**Full name of responsible person**  
Mohammad Ali Nilforoushzadeh  
**Position**  
Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Dermatology  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Skin and Stem cell Research Center of Tehran

University of Medical Sciences  
**Full name of responsible person**  
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researcher  
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Cellular and Molecular Biology  
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dr.sonazare@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable