

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the efficacy of conditioned medium derived from human umbilical cord Wharton jelly mesenchymal stem cells in comparison with intralesional triamcinolone in the treatment of alopecia areata

Protocol summary

Study aim

Evaluation of the efficacy of conditioned medium derived from human umbilical cord Wharton jelly mesenchymal stem cells in comparison with intralesional triamcinolone in the treatment of alopecia areata

Design

This phase 1 study is performed on 28 patients with hair loss. In group A, 6 sessions were given to each patient at intervals of 2 weeks and in each session, medium conditioning was injected (intervention) and in group B, triamcinolone was injected to patient for three sessions at intervals of one month per session (control).). All patients before the treatment and 2 months after the second visit and photos are taken by digital camera and tricoscan.

Settings and conduct

This project is carried out in the Skin and Stem Cell Research Center of Tehran University of Medical Sciences. In group A, 6 sessions were given for each patient at 2-week intervals and in each session, medium conditioning was injected, and in group B, triamcinolone was injected for 3 sessions per patient at one-month intervals.

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 group A, 6 sessions were given for each patient at 2-week intervals and in each session, medium conditioning was injected (intervention), and in group B, triamcinolone was injected for 3 sessions per patient at one-month

intervals (control).

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: **IRCT20200127046282N10**

Registration date: **2022-03-30, 1401/01/10**

Registration timing: **prospective**

Last update: **2022-03-30, 1401/01/10**

Update count: **0**

Registration date

2022-03-30, 1401/01/10

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

Recruitment complete

Funding source

Expected recruitment start date

2022-04-19, 1401/01/30

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of conditioned medium derived from human umbilical cord Wharton jelly mesenchymal stem cells in comparison with intralesional triamcinolone in the treatment of alopecia areata

Public title
Evaluation of the efficacy of conditioned medium derived from human umbilical cord Wharton jelly mesenchymal stem cells 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 **50 years** old

Gender
Both

Phase
1

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Each patient is randomly divided into one of two groups A or B: in group A for each patient 6 sessions at intervals of 2 weeks and in each session medium conditioning is injected and in group B for patient 3 sessions with an interval of 1 month Triamcinolone is injected. The outcome assessor and the blind data analyzer will be considered.

Placebo
Not 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 University of Medical Sciences, Keshavarz blvd.
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2022-03-16, 1400/12/25
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.1519

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

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 medium conditioning for 6 sessions 2 weeks apart by injection.

Category

Treatment - Other

2

Description

Control group: Patients receive triamcinolone injection for three sessions, one month apart.

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

Elham Behrangi

Street address

No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran

City

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1937957511

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Email

elham.behrangi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Mohammad Ali Nilforoushzadeh

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No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran

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Nilforoosh@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Skin and Stem Cell Research Center, 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, 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, Tehran
University of Medical Sciences
Full name of responsible person
Elham Behrangi
Position
Associate 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)

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