

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Therapeutic results of stem cells isolated from hair follicles in baldness treatment

Protocol summary

Study aim

Evaluation of the therapeutic results of using stem cells isolated from hair follicles for the treatment of baldness

Design

Clinical trial on 10 patients without randomization and blinding, phase 3 and with placebo

Settings and conduct

In this study, male patients with baldness will be investigated. Identification and confirmation of patients with baldness will be done by observing an increase in the number of end-point hairs, or a decrease in the number of hairs in a physical examination and phototrichogram along with a negative hair pull test.

Participants/Inclusion and exclusion criteria

Inclusion criteria were baldness stage 3 to 5 according to Norwood-Hamilton classification and consent to participate in the study. Patients with sepsis, immune system suppression, cancer and use of medical treatments for baldness (such as finasteride, dutasteride, or antiandrogens) during the past 12 months will be excluded.

Intervention groups

Intervention group: After extracting the scalp tissues through the punch biopsy method, the scalp tissue will be cut into 2 mm x 2 mm strips, and the excess fat tissue will be separated along with the skin. These strips will be collected and separated slowly in 1.2 ml of the physiological solution under sterile conditions (vertical layer flow hood) and then centrifuged for 60 seconds at 80 rpm. Then sediment cells will be mechanically injected into the scalp of bald patients. Control group: After dividing the scalp into different parts, a placebo (normal saline) will be injected into one of these areas to compare the results with the intervention.

Main outcome variables

Hair growth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100314003566N12**

Registration date: **2023-02-06, 1401/11/17**

Registration timing: **prospective**

Last update: **2023-02-06, 1401/11/17**

Update count: **0**

Registration date

2023-02-06, 1401/11/17

Registrant information

Name

Hamide Azimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1540 6612

Email address

azimih@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-19, 1401/11/30

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic results of stem cells isolated from hair follicles in baldness treatment

Public title

Baldness treatment using stem cells

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Baldness stage 3 to 5 according to Norwood-Hamilton classification Consent to participate in the study

Exclusion criteria:

Sepsis Immune system suppression Cancer Use of medical treatments for baldness (such as finasteride, dutasteride, or antiandrogens) during the past 12 months

Age

From **30 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee Of Tabriz University Of Medical Sciences.

Street address

Third Floor, Central Building of Number 2, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Approval date

2023-01-23, 1401/11/03

Ethics committee reference number

IR.TBZMED.REC.1401.961

Health conditions studied**1****Description of health condition studied**

Baldness

ICD-10 code

L65.9

ICD-10 code description

Nonscarring hair loss, unspecified

Primary outcomes**1****Description**

Hair growth

Timepoint

3 weeks, 9 weeks, 16 weeks and 23 weeks after the intervention

Method of measurement

Hair growth in patients will be objective compared by the dermatologist's opinion after the last treatment using photography with the initial assessment done before and after treatment and between the treated area of the intervention and also the control area where the placebo injection was done.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: After extracting the scalp tissues through the punch biopsy method, the scalp tissue will be cut into 2 mm x 2 mm strips, and the excess fat tissue will be separated along with the skin. These strips will be collected and separated slowly in 1.2 ml of the physiological solution under sterile conditions (vertical layer flow hood) and then centrifuged for 60 seconds at 80 rpm. Then sediment cells will be mechanically injected into the scalp of bald patients.

Category

Treatment - Drugs

2**Description**

Control group: After dividing the scalp into different parts, a placebo (normal saline) will be injected into one of these areas to compare the results with the intervention.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Sina Hospital

Full name of responsible person

Dr.Hamideh Azimi

Street address

Dermatology ward, Sina Hospital, Azadi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Abolghasem Juiban

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Third Floor, Central Building of Number 2, Golgasht Street

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Hamide Azimi

Position

Dermatologist

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Web page address**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

No - There is not 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

Study data is categorized and coded with no identifiable individuals.

When the data will become available and for how long

Access to study data after publication of the result is available in the journal.

To whom data/document is available

Anyone interested in using the data can access the study data.

Under which criteria data/document could be used

Study data can be used for comparison with other results.

From where data/document is obtainable

Refer to the study's scientific or public accountability person for data.

What processes are involved for a request to access data/document

The request will be sent by email to person responsible for scientific or public inquiries.

Comments