Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Efficacy and safety of exosome therapy versus mesotherapy on male and female pattern hair loss: Randomized controlled trial

Protocol summary

Study aim

Determining the efficacy and side effects of exosome therapy compared to mesotherapy in patients with pattern hair loss

Design

An open-label, phase 2–3 randomized clinical trial will be conducted on 60 patients. Simple randomization using the block balanced randomization method will be applied, and the randomization list will be generated via the website [randomization.com](http://www.randomization.com).

Settings and conduct

Patients with pattern hair loss who meet the inclusion criteria will be recruited from the dermatology clinic at Bouali Hospital,in Sari, Mazandaran Province, Iran

Participants/Inclusion and exclusion criteria

Age range:18 to 60 years ,type of hair loss: Male and female pattern hair loss based on the Hamilton and Ludwig scales, Lack of satisfactory response to medications, follicular unit transplantation, and hormonal therapies, History of autoimmune diseases ,Diabetes mellitus ,Pregnancy and breastfeeding ,Previous allergic reaction to treatment components, Diagnosis of telogen effluvium or other types of alopecia (e.g., alopecia areata)

Intervention groups

Group A will include patients receiving exosome therapy alone, administered once a month for three months. Group B will include patients receiving a combination of exosome therapy and mesotherapy, administered once a month for three months. Group C will include patients receiving mesotherapy alone، administered once a month for three months All patients will be evaluated one month after the final treatment session to assess their response to therapy.

Main outcome variables

PGAIS(Patient Global Aesthetic Improvement Scale)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160427027636N8**
Registration date: **2025-08-02, 1404/05/11**
Registration timing: **prospective**

Last update: **2025-08-02, 1404/05/11**
Update count: **0**

Registration date

2025-08-02, 1404/05/11

Registrant information

Name

Ghasem Rahmatpour Rokni

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3322 1755

Email address

gh.rahmatpour@mazums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy and safety of exosome therapy versus mesotherapy on male and female pattern hair loss: Randomized controlled trial

Public title
Efficacy and safety of exosome therapy versus mesotherapy on male and female pattern hair

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
"Man and woman aged 18 to 60 years, healthy and not pregnant" "Male pattern hair loss (MPHL) grade III to IV based on the Norwood-Hamilton scale" "Female pattern hair loss (FPHL) with early localized or diffuse hair loss corresponding to grade I-3 to III based on the Ludwig scale" Patients who are in a stable state of improvement or worsening after one year of treatment with medications such as minoxidil, finasteride, dutasteride, and spironolactone, or who continue to experience hair loss after six months of medication use. Patients who have undergone follicular unit extraction and transplantation and experience hair thinning and shedding in both the transplanted and non-transplanted areas of the scalp one year after surgery. Patients undergoing treatment and monitoring for estrogen, progesterone, testosterone, and other pituitary or thyroid replacement therapies, yet continue to experience hair thinning and shedding. Willingness and ability to provide written informed consent for photography and authorization prior to undergoing any study-related procedures.

Exclusion criteria:

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
A patient randomization list will be generated using the balanced block randomization method with the help of an online randomization website. Then, a list will be generated using the original generator section of *randomization.com* with blocks of 6. These will be placed sequentially into sealed envelopes. After preparing the sealed envelopes, the list will be destroyed. Patients will be randomly assigned in a 1:1:1 ratio into one of three groups. Group A will include patients who will receive *exosome therapy alone*, once a month for three months. Group B will include patients who will receive a *combination of exosome therapy and mesotherapy, once a month for three months. Group C will include patients who will receive *mesotherapy alone*, once a month for three months. All patients will be evaluated one month after the final intervention session to assess their response to treatment.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee, Mazandaran University of Medical Sciences

Street address
Mazandaran University of Medical Sciences, Moalem square

City
Sari

Province
Mazandaran

Postal code
4741948178

Approval date
2025-07-12, 1404/04/21

Ethics committee reference number
IR.MAZUMS.REC.1404.145

Health conditions studied

1

Description of health condition studied
Androgenetic alopecia with male and female pattern hair loss

ICD-10 code
L64

ICD-10 code description
Androgenetic alopecia (male and female pattern hair loss)

Primary outcomes

1

Description
Blinded investigator global aesthetic improvement scale

Timepoint
Assessments will be conducted at baseline, monthly after each injection for a total of three months, and once more in the fourth month, which corresponds to one month after the final treatment session.

Method of measurement

Ludwig and Hamilton scale questionnaire

Secondary outcomes

1

Description
patient satisfaction
Timepoint
"At the end of four months from the start of the intervention"
Method of measurement
Questionnaire

2

Description
Patient global aesthetic improvement scale
Timepoint
"At the end of four months from the start of the intervention"
Method of measurement
Questionnaire

3

Description
reported side effects
Timepoint
"At the end of four months from the start of the intervention"
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: Group A will include patients who receive exosome therapy alone once a month for three months
Category
Treatment - Drugs

2

Description
Intervention group: Group B will include patients who receive a combination of exosome and mesotherapy once a month for three months.
Category
Treatment - Drugs

3

Description
Intervention group: Group C will include patients who receive mesotherapy alone once a month for three months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Dermatology, Bou-Ali Sina Hospital
Full name of responsible person
Ghasem Rahmatpour Rokni
Street address
Mazandaran Province, Sari, Pasdaran Blvd, H23J+9PJ, 48158 38477, Iran
City
Sari
Province
Mazandaran
Postal code
4815838477
Phone
+98 11 3334 3011
Fax
+98 11 3334 3011
Email
Bou_Ali_hospital@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati
Street address
Mazandaran University Of Medical Sciences, The beginning of the highway Valiasser, Joybar Three-way, Imam (AS) square
City
Sari
Province
Mazandaran
Postal code
4878415466
Phone
+98 11 3434 7021
Email
ethics@mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Ghasem Rahmatpour Rokni, MD

Position

Assistant Professor of Dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Bualisina Hospital, Pasdaran Boulevard, Sari

City

Sari

Province

Mazandaran

Postal code

3847748158

Phone

+98 11 3334 2334

Fax

Email

dr.rokni@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ghasem Rahmatpour Rokni

Position

Assistant Professor of Dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Bu-Ali Sina hospital

City

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Province

Mazandaran

Postal code

3847748158

Phone

+98 11 3322 1755

Fax

Email

dr.rokni@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ghasem Rahmatpour Rokni

Position

Assistant Professor of Dermatology

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Specialist

Other areas of specialty/work

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Fax

Email

dr.rokni@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not 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

Title: Dataset and Documentation for the Clinical Trial on Exosome Therapy vs. Mesotherapy for Hair Loss Details: The dataset includes de-identified individual participant data related to the primary outcome (blinded Investigator Global Aesthetic Improvement Scale, blinded-IGAIS) and secondary outcomes (Patient Global Aesthetic Improvement Scales, PGAIS; patient satisfaction; reported side-effects). Additional documentation includes the study protocol, statistical analysis plan, and case report forms. Only de-identified data will be shared to protect participant privacy. Aggregate data, such as summary statistics and results published in the final report, may also be shared.

When the data will become available and for how long

Data and documentation will be available starting 6 months after the publication of the primary study results

and will remain accessible for a period of 5 years.

To whom data/document is available

Access to the data and documentation will be restricted to academic researchers affiliated with recognized universities or research institutions. Requests from industry researchers may be considered on a case-by-case basis, provided they demonstrate a clear scientific purpose aligned with the study's objectives.

Under which criteria data/document could be used

The data and documentation may be used for non-commercial research purposes, such as secondary analyses, meta-analyses, or validation studies, provided they align with the original study's objectives. Users must agree to: Not attempt to re-identify participants. Use the data solely for the approved research purpose. Cite the original study and acknowledge Mazandaran University of Medical Sciences in any publications or presentations. Submit a formal request detailing the intended use, including the proposed analysis plan. Sign a data use agreement ensuring compliance with ethical standards and data protection regulations. Requests will be reviewed by the study's principal investigator and the Mazandaran University of Medical Sciences Research Ethics Committee.

From where data/document is obtainable

Requests for data or documentation should be directed to the principal investigator, Dr. Ghasem Rahmatpour Rokni, via email at dr.rokni@yahoo.com Vice-Chancellor for Research and Technology Mazandaran University of Medical Sciences Moallem Square, Sari, Mazandaran, Iran Phone: 09125443956 Requests can also be submitted through the university's research portal: [insert website, if applicable]. The principal investigator or a designated member of the research team will respond to inquiries.

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

Applicants must submit a formal request via email or the university's research portal, including a detailed proposal outlining the intended use of the data/documents, the research objectives, and the proposed analysis plan. The request will be reviewed by the principal investigator and the Mazandaran University of Medical Sciences Research Ethics Committee within 4 weeks. If approved, the applicant will be required to sign a data use agreement. De-identified data and/or documentation will be provided in a secure format (e.g., encrypted files) within 2 weeks of agreement signing. The entire process, from request submission to data delivery, is expected to take approximately 6–8 weeks, barring unforeseen delays.

Comments