Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy and safety evaluation of extravesicle, derived from Wharton's jelly's mesenchymal cells of the umbilical cord, injection in androgenetic alopecia.

Protocol summary

Study aim

investigating the effect of the extravesicle solution injection on androgenetic alopecia severity based on the Norwood Hamilton scale in men and the Ludwig scale in women 5 months after the start of the therapy. investigating the effect of the extravesicle solution injection on hair density based on the trichoscan images 5 months after the start of the therapy. investigating the effect of the extravesicle solution injection on telogen phase hair count based on the pull test 5 months after the start of the therapy. investigating the side effects of the extravesicle solution injectionin in each treatmen session and 5 months after the start of the therapy.

Design

clinical trial without a control group,phase 1 study on 10 patients

Settings and conduct

10 volunteer patients are selected from dermatology clinic clients at Rasool Hospital according to the inclusion and exclusion criteria. Extravesicle is injected in three treatment sessions at a one month interval.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Ladies and gentlemen with androgenetic alopecia,Age 18 years and above and less than 50 years old,Hamilton score 2 to 5 in men Ludwig score 1 to 3 in women,Complete patient consent to participate in the project Exclusion criteria:Platelet dysfunction,Thrombocytopenia,Anticoagulant drug use,Malignancy,Chemotherapy within 5 years,Sepsis,Smoking,Pregnancy,Ulcer or infection at the site of treatment,Do not receive any topical or systemic medication in the last 3 months,Women with hyperprolactinemia,Women with hormonal dysfunction or polycystic ovarian disease

Intervention groups

A group of 10 people will be treated with extravesicle injection on three treatment sessions. The interval between each treatment session is one month.

Main outcome variables

Change in alopecia severity,telogen phase hair count,hair density,physician assessment,patient assessment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140624018210N13**
Registration date: **2022-09-03, 1401/06/12**
Registration timing: **prospective**

Last update: **2022-09-03, 1401/06/12**
Update count: **0**

Registration date

2022-09-03, 1401/06/12

Registrant information

Name
Elham Behrangi
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6650 2040
Email address
behrangi.e@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety evaluation of extravesicle, derived from Wharton's jelly's mesenchymal cells of the umbilical cord, injection in androgenetic alopecia.

Public title

Efficacy evaluation of extravesicle, derived from Wharton's jelly's mesenchymal cells of the umbilical cord, injection in androgenetic alopecia.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ladies and gentlemen with androgenetic alopecia Age 18 years and above and less than 50 years old Hamilton score 2 to 5 in men Ludwig score 1 to 3 in women Complete patient consent to participate in the project

Exclusion criteria:

Platelet dysfunction Thrombocytopenia Anticoagulant drug use Malignancy Chemotherapy within 5 years Sepsis Smoking Pregnancy Ulcer or infection at the site of treatment Do not receive any topical or systemic medication in the last 3 months Women with hyperprolactinemia Women with hormonal dysfunction or polycystic ovarian disease

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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,Ghods Street,Keshavarz Boulevard,Tehran,Iran

City

Tehran

Province

Tehran

Postal code

1111111111

Approval date

2021-10-23, 1400/08/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1177

Health conditions studied

1

Description of health condition studied

Androgenetic alopecia

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

Primary outcomes

1

Description

Alopecia severity

Timepoint

Before the start of the trial and two months after the last session

Method of measurement

Rate of change in the clinical severity of alopecia is measured by imaging with visioface. hamilton scale 1 to 6 in men.Ludwig scale 1 to 3 in women

2

Description

The amount of hair in the telogen phase

Timepoint

Before the beginning of the trial and two months after the last session

Method of measurement

The amount of hair in the telogen phase is measured by pull test

3

Description

Hair density

Timepoint

Before the beginning of the trial and two months after the last session

Method of measurement
Hair density is measured by trichoscan

4

Description
Patient satisfaction of treatment
Timepoint
Two months after the last session of treatment
Method of measurement
Patient global assessment score

5

Description
Physician satisfaction of treatment
Timepoint
Two months after the last session of treatment
Method of measurement
Physician global assessment score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: a group of 10 people is treated with extravesicle solution derived from Wharton's jelly's mesenchymal cells of the umbilical cord.The treatment sessions are three sessions with an interval of one month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
Tahereh Rahimi
Street address
Rasool Akram Hospital, Niayesh street, Shahara
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6690 9257
Email
mtaherehrahimi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Skin and Stem Cell Research Center
Full name of responsible person
Mohammad Ali Nilforoushzadeh
Street address
No 4. Maryam Alley. South Kamranyeh Street, Skin and Stem Cell Research Center
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 2221 2537
Email
Afsaneh.najafi@yahoo.com
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
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
Iran University of Medical Sciences
Full name of responsible person
Dr Elham Behrangi
Position
Professor
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Dermatology Department,Rasool Hospital,Satarkhan Street
City
Tehran
Province
Tehran
Postal code

1445613131
Phone
+98 21 6650 2040
Fax
+98 21 6650 2040
Email
behrangi.e@iums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Elham Behrangi
Position
Professor
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Dermatology Department,Rasool Hospital,Satarkhan Street
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6650 2040
Fax
+98 21 6650 2040
Email
behrangi.e@iums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Elham Behrangi
Position
Professor
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Dermatology Department,Rasool Hospital,Satarkhan Street
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6650 2040
Fax
+98 21 6650 2040
Email
behrangi.e@iums.ac.ir
Web page address

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