

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effectiveness of conditioned medium derived from Wharton's jelly mesenchymal stem cells, extracellular vesicles derived from Wharton's jelly and triamcinolone in the treatment of lichen Plano Pilaris

Protocol summary

Study aim

Comparing the effectiveness of conditioned medium derived from Wharton's jelly mesenchymal stem cells, extracellular vesicles derived from Wharton's jelly and triamcinolone in the treatment of lichen Plano Pilaris

Design

This study is conducted in phase 1 and 2 on 30 patients with lichen planopilaris. All patients are photographed by a digital camera and tricoscan before treatment and at each visit session. To determine the recovery rate, at the end of the study, the photos of the patients are examined by 2 neutral dermatologists. Also, the satisfaction of the patients is recorded and the results are compared.

Settings and conduct

This project is carried out at the Skin and Stem Cell Research Center of Tehran University of Medical Sciences on lichen planopilaris patients. There are two intervention groups and one control group, and the patient and the data evaluator do not know about the intervention groups and are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18-60 years, lichen planopilaris disease has been proven. Exclusion criteria: breastfeeding, pregnancy, infectious diseases

Intervention groups

Control group: 10 patients are injected with triamcinolone 5 times with an interval of 1 month.
Intervention group: 10 patients are injected 5 times with an interval of 1 month under conditioned medium derived from Wharton's jelly mesenchymal stem cells.
Intervention group: 10 patients are injected 5 times with an interval of 1 month with extracellular vesicles derived from Wharton's jelly mesenchymal stem cells.

Main outcome variables

Response to treatment, The amount of hair loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N29**

Registration date: **2023-05-06, 1402/02/16**

Registration timing: **prospective**

Last update: **2023-05-06, 1402/02/16**

Update count: **0**

Registration date

2023-05-06, 1402/02/16

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

2023-05-10, 1402/02/20

Expected recruitment end date

2023-09-11, 1402/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of conditioned medium derived from Wharton's jelly mesenchymal stem cells, extracellular vesicles derived from Wharton's jelly and triamcinolone in the treatment of lichen Plano Pilaris

Public title
Comparing the effectiveness of two cell products and triamcinolone drug in the treatment of lichen planopilaris

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-60 years Lichen planopilaris disease has been proven
Exclusion criteria:
breastfeeding pregnancy Infectious diseases

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

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The product is used for injection in a syringe covered with aluminum foil. The participant and the data analyst will not know about the intervention groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz blvd

City
Tehran

Province
Tehran

Postal code
1937957511

Approval date
2023-04-10, 1402/01/21

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.024

Health conditions studied

1

Description of health condition studied

Lichen Planopilaris

ICD-10 code

L66

ICD-10 code description

Cicatricial alopecia [scarring hair loss]

Primary outcomes

1

Description

Response to treatment

Timepoint

0 and 6 months after the start of the study

Method of measurement

Lichen plano pilaris activity index

2

Description

The amount of hair loss

Timepoint

Before starting treatment and one month after the end of the treatment period

Method of measurement

Trichoscan

Secondary outcomes

1

Description

The level of satisfaction with treatment qualitatively

Timepoint

2 and 6 months after the start of treatment

Method of measurement

In the qualitative questionnaire (excellent effect, good, medium, low, ineffective)

2

Description

side effects

Timepoint

Before starting treatment and one month after the end of

the treatment period
Method of measurement
Questionnaire and visit

3

Description
effectiveness

Timepoint
Before starting treatment and one month after the end of the treatment period

Method of measurement
Questionnaire and visit

Intervention groups

1

Description
Control group: 10 patients were injected with 3 cc of triamcinolone (Jaber Ebne Hayyan company) 5 times with a 1-month interval.

Category
Treatment - Other

2

Description
Intervention group: 10 patients are injected with 3 cc of mesenchymal stem cell medium conditioned by Wharton jelly (Zist Sakht Bonyan Pars company) 5 times at 1 month intervals.

Category
Treatment - Other

3

Description
Intervention group: 10 patients are injected with 3 cc of extracellular vesicles derived from Wharton jelly mesenchymal stem cells (Zist Sakht Bonyan Pars company) 5 times with an interval of 1 month.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Skin and Stem cell Research Center Clinic, Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Nilforoushzadeh
Street address
No 4, Maryam Alley, South Kamraniyeh Street
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Tehran
Province
Tehran
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1937957511
Phone
+98 21 2665 7438
Email
nilforoosh@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotoohi
Street address
Central University Organization, sixth floor, Vice Chancellor for Research and Technology, corner of Quds Street, Keshavarz Boulevard
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Tehran
Province
Tehran
Postal code
1937957511
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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No 4, Maryam Alley, South Kamraniyeh Street

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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

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Full name of responsible person

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Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Cellular and Molecular Biology

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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