Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 planopillaris 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 planopillaris

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

City

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1937957511

Phone

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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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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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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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Latest degree
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Other areas of specialty/work
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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