

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of the safety and effectiveness of Wharton jelly mesenchymal stem cell condition medium spray and erbium laser with triamcinolone and erbium laser in the treatment of resistant hand eczema

Protocol summary

Study aim

Comparison of the safety and effectiveness of Wharton jelly mesenchymal stem cell condition medium spray and erbium laser with triamcinolone and erbium laser in the treatment of resistant hand eczema

Design

A clinical trial with a control group and an intervention group, with parallel groups, double-blind (outcome assessor and patient), randomized based on the table of random numbers, phase 1-2 on 30 patients with hand eczema

Settings and conduct

The place of study is the skin and stem cell research center clinic of Tehran University of Medical Sciences. In this study, blinding was done and the outcome assessor and the patient will not know the type of treatment. There is an intervention group and a control group. Three treatment sessions will be done with an interval of one month.

Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy patients with hand eczema who have not used any topical medication in the past 2 weeks or any systemic medication in the past month. Exclusion criteria: pregnancy, breastfeeding, severe sensitivity to the study drug

Intervention groups

Intervention group: 10 patients are subjected to local spray of Wharton's jelly mesenchymal stem cell conditioned medium and erbium laser 3 times with an interval of 1 month. Control group: 10 patients are subjected to topical triamcinolone spray and erbium laser 3 times with an interval of 1 month.

Main outcome variables

Reduce or improve hand eczema

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N26**

Registration date: **2023-04-21, 1402/02/01**

Registration timing: **prospective**

Last update: **2023-04-21, 1402/02/01**

Update count: **0**

Registration date

2023-04-21, 1402/02/01

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

2023-05-05, 1402/02/15

Expected recruitment end date

2023-08-06, 1402/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the safety and effectiveness of Wharton jelly mesenchymal stem cell conditioned medium spray and erbium laser with triamcinolone and erbium laser in the treatment of resistant hand eczema

Public title

Comparison of the safety and effectiveness of local spray stem cells conditioned medium and erbium laser compared to triamcinolone and erbium laser in the treatment of hand eczema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy patients with hand eczema who have not used any topical medication in the past 2 weeks or any systemic medication in the past month.

Exclusion criteria:

Pregnancy Breastfeeding Severe sensitivity to the study drug

Age

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

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Considering that the number of cases in this research plan is 20 people, which should be randomly divided into two groups of 10 people, therefore, the randomization method in this research plan will be done in such a way that the patients will be randomly selected using the systematic randomization method and the resulting numbers. From the computer, they will be divided into two groups of 10 people.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients and the data analyst will not know the type of treatment, so the study will be conducted in a double-blind manner.

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.1402.026

Health conditions studied

1

Description of health condition studied

hand eczema

ICD-10 code

L20.8

ICD-10 code description

Diseases of the skin and subcutaneous tissue

Primary outcomes

1

Description

Reduce or improve hand eczema

Timepoint

before and two weeks after the end of the study

Method of measurement

Using Eczema Extent and Severity Scale (EASI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 10 patients are subjected to local spray of Wharton's jelly mesenchymal stem cell conditioned medium and erbium laser 3 times with an interval of 1 month.

Category

Treatment - Other

2

Description

Control group: 10 patients are subjected to topical triamcinolone spray and erbium laser 3 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

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No 4, Maryam Alley, South Kamraniyeh Street

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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
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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

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
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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

Contact

Name of organization / entity

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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