

# 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

**Street address**

No 4, Maryam Alley, South Kamraniyeh Street

**City**

Tehran

**Province**

Tehran

**Postal code**

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

**City**

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

**Street address**

No 4, Maryam Alley, South Kamraniyeh Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2665 7438

**Email**

sonazarebio@gmail.com

**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

**Street address**

No 4, Maryam Alley, South Kamraniyeh Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2665 7438

**Email**

nilforoosh@sina.tums.ac.ir

## Person responsible for updating data

### 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

**Street address**

No 4, Maryam Alley, South Kamraniyeh Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2665 7438

**Email**

sonazarebio@gmail.com

## 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