

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Safety and efficacy of injection of Umbilical Cord Blood Serum derived exosomes for skin lesions in patients with chronic psoriasis(Phase 1 of clinical trial)

Protocol summary

Study aim

Investigating the safety and effectiveness of the injection of exosomes derived from umbilical cord blood serum(UCBS) in improving the skin lesions of patients with psoriasis

Design

Clinical trial with 4 groups, three intervention groups and one control group, double blind, randomized, phase 1 on 30 patients. A simple randomization method was used for randomization.

Settings and conduct

Intradermal injection in one-to-one dimensions with a volume of 1 ML in the lesion area in the skin and hair research center with double blind study of the therapist and the patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria:older than 18 years;Patients with psoriasis for at least 6 months;PASI(Psoriasis Area Severity Index) index 3 to 12;DLQI(Dermatology Life Quality Index):1 to 3 Exclusion criteria:treatment area Infection; malignancy; Pregnancy; Breastfeeding; Immunosuppression; Systemic diseases (Such as high blood pressure; Diabetes; Heart disease; Cancer; Kidney and Liver)

Intervention groups

Patients are divided into 3 groups. Intervention groups 1, 2, and 3 will be treated with exosome derived from umbilical cord blood serum at a dose of 50, 100, and 200 micrograms per milliliter per square centimeter, and the injection will be done once a month for 3 months. Meanwhile, a lesion with the same severity is considered as a positive control treated with corticosteroid ointment for the same person. The injection of each of the study groups will be done in the next dose if there are no side effects in the first dose after 4 weeks.

Main outcome variables

Complications of treatment; recovery rate; recovery

time; patient satisfaction; the amount of inflammatory factors; The thickness of epidermis and dermis;Psoriasis Area Severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221130056672N4**

Registration date: **2024-01-21, 1402/11/01**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-21, 1402/11/01**

Update count: **0**

Registration date

2024-01-21, 1402/11/01

Registrant information

Name

EHSAN Taghiabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2665 7541

Email address

etaghiabadi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-20, 1402/10/30

Expected recruitment end date

2024-05-18, 1403/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of injection of Umbilical Cord Blood Serum derived exosomes for skin lesions in patients with chronic psoriasis(Phase 1 of clinical trial)

Public title

Safety and efficacy of injection of Umbilical Cord Blood Serum derived exosomes for skin lesions in patients with chronic psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age older than 18 years Patients with chronic plaque psoriasis for at least 6 months PASI index 3 to 12 Lesion intensity 1 to 3 (rating 0 to 5) Lack of proper response to standard treatments including local treatments, light therapy and systemic treatments Not creating new lesions or increasing the size of previous lesions in the last 3 months Skin lesion with BSA higher than 10%

Exclusion criteria:

Use of systemic immunosuppressive drugs in the last 4 weeks and topical drugs except emollients in the last 2 weeks Severe underlying disease (liver-kidney and heart failure) Increase of liver enzymes > 3 times normal and creatinine > 2 Patients with diabetes mellitus, patients with a history of hepatitis B, C or HIV Pregnant and nursing mothers Patients with immunodeficiency, patients with malignancy, presence of debilitating disease, presence of active infection

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each patient randomly receives one of the doses of 50, 100, or 200 three times with an interval of one month, and another lesion in the same patient is treated with corticosteroid ointment as a positive control.

Randomization (investigator's opinion)

Randomized

Randomization description

Using the simple randomization method, the patients who visit the Dr. Nilfroshzadeh's skin clinic are placed in 3 groups, so that one envelope is randomly selected for each patient from the number of 30 sealed envelopes. Inside each envelope is the letter A, B or C. Patients of

groups A, B, and C are injected with concentrations of 50, 100, and 200 microgram per milliliter per square centimeter of the skin lesion, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

The injection and use of the ointment is performed in two different lesions in the same patient, the patients are not told which is the main treatment. The clinical care provider is unaware of the dose (50/100/200 µg/ml) used and the doctor evaluating the outcome is aware that it is unclear which lesion was treated with injection and which was treated with ointment.

Placebo

Used

Assignment

Crossover

Other design features

After the injection, the patients are followed up for 3 months to measure the efficacy and safety. Injection is done in 3 different doses to identify the optimal dose for the treatment of patients, also another lesion in the same patient is treated with corticosteroid ointment as a positive control. If it is successful, it means that with no side effects such as redness, itching, peeling from the lesion site, so that if no adverse event occurs, we will start the intervention with the next dose, each of the selected doses in three times with an interval. It will be injected for a month, and in the meantime, we will follow up the patients by being in contact with the patients and receiving pictures of the lesion site. Each of the doses (50, 100, and 200 micrograms per square centimeter in one milliliter), the injection will be done once every month for 3 months, then at the end of the fourth month, the injection site will be sampled in order to check the healing improvement. The lesion and the reduction of the level of inflammatory factors will be done at the molecular level.

Secondary Ids

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Research Ethics Committees of Research Institute for Oncology, Hematology and Cell Therapy - Tehran

Street address

No.4, 4th floor, Maryam dead end. South Kamraniyeh

City

Tehran

Province

Tehran

Postal code

1937957511

Approval date

2024-01-07, 1402/10/17

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Psoriasis

ICD-10 code

L40

ICD-10 code description

Psoriasis

Primary outcomes

1

Description

PASI index: Psoriasis Area Severity Index (PASI)

Timepoint

The measurement will be at the beginning of the study (before the start of the intervention) and 7, 14, 21, 30 and 60 days after the first injection

Method of measurement

analysis and impact of data using biometric like High-Frequency Sonography

Secondary outcomes

1

Description

safety

Timepoint

At the beginning of the intervention, in each re-visit session and one month after the end of the treatment period (four months after the start of the treatment)

Method of measurement

Patient history

Intervention groups

1

Description

The first intervention group: under treatment with local injection of exosome (derived from cord blood serum purchased from Apsa company) with a concentration of 50 micrograms per milliliter: exosomes derived from human cord serum per square centimeter of the skin lesion injected for 3 It will be done once a month.

Category

Treatment - Other

2

Description

Control group: topical use of fluocinolone corticosteroid ointment from Tehran tehranchemie factory every morning and night.

Category

3

Description

The second intervention group: under treatment with local injection of exosome (derived from cord blood serum purchased from Apsa company) 100 micrograms per milliliter of exosomes derived from human cord serum per square centimeter of the skin lesion injected once every month for 3 months will be done regularly.

Category

Treatment - Other

4

Description

The third intervention group: under treatment with local injection of exosome (derived from cord blood serum purchased from Apsa company) 200 micrograms per milliliter of exosomes derived from human cord serum per square centimeter of the skin lesion injected once every month for 3 months will be done regularly.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilfrooshzadeh

Street address

No.4 Maryam Dead End South Kamraniyeh, Andarzgo
Blv, Tehran Province, Tehran

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2665 7541

Email

etaghiajadi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilfroushzadeh

Street address

Research and Technology Deputy, 6th floor , Quds St,
Tehran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1937957511

Phone
+98 21 2665 7438

Email
etaghlabadi@sina.tums.ac.ir

Grant name
Tehran University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Tehran University of Medical Sciences

Full name of responsible person
Ehsan Taghiabadi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Applied cell sciences

Street address
No.4, 4th floor, Maryam dead end. South Kamraniyeh

City
Tehran

Province
Tehran

Postal code
1937957511

Phone
+98 21 2665 7438

Email
etaghlabadi@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ehsan Taghiabadi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Biotechnology

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City
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Phone
+98 21 2665 7438

Email
etaghlabadi@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ehsan Taghiabadi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Biotechnology

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o. 4 , 4th floor, Maryam dead end, South Kamraniyeh

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Phone
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Email
etaghlabadi@sina.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after de-identifying individuals.

When the data will become available and for how long

Six months after the publication and printing of the article

To whom data/document is available

Academic researchers and experts

Under which criteria data/document could be used

In order to analyze the results of the study outcomes

From where data/document is obtainable

etaghiaadi@sina.tums.ac.ir

What processes are involved for a request to access data/document

It can be submitted after review by the Research Council of the Skin and Stem Cell Research Center of Tehran University of Medical Sciences, which usually takes 2 to 3 months.

Comments