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 ۱ 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 ۱ 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

IR.TUMS.HORCSCT.REC.1402.055

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
Treatment - Drugs

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
etaghiabadi@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
etaghiabadi@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
etaghiabadi@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
Street address
No. 4 , 4th floor, Maryam dead end, South Kamraniyeh
City
Tehran
Province
Tehran
Postal code
1937957511
Phone
+98 21 2665 7438
Email
etaghiabadi@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
Street address
o. 4 , 4th floor, Maryam dead end, South Kamraniyeh
City
Tehran
Province
Tehran
Postal code
1937957511
Phone
+98 21 2665 7438
Email
etaghiabadi@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

etaghiabadi@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