Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Assessment of Safety and Efficacy of Intradermal Injection of Wharton's jelly Mesenchymal Cells Derived Extracellular Vesicles With CO2 Laser in Treatment of Melasma(A randomized controlled intervention study)

Protocol summary

Study aim

Investigating the effect of local injection of extracellular vesicles derived from Wharton jelly mesenchymal cells along with CO2 laser in the treatment of melasma

Design

Clinical trial with 3 groups, 2 intervention groups and a control group, parallel groups, randomized, phase 1-2 on 30 patients, simple randomization method was used for randomization.

Settings and conduct

Patient information is collected through a questionnaire and photography in reference to the Skin and Stem Cell Research Center of Tehran University of Medical Sciences. Patients with melasma in the face area are divided into 2 intervention groups and a control group. The control group is treated with CO2 laser with a wavelength of 30 joules and lasts for 5 minutes. The intervention group is treated with interdermal injection (5-15 mm) at an angle of 45 degrees with 0.5 cm intervals, the entire lesion in the area of the cheek to the jaw on each side of the face with volume1 C.C. is treated by a specialist physician. The duration of the treatment is 4 sessions with an interval of 1 month.

Participants/Inclusion and exclusion criteria

Inclusion Criteria:women aged 18-50 years; Full satisfaction of patients for participation Exclusion criteria: Previous treatment of melasma,infection in the treatment area,malignant patients

Intervention groups

Patients are divided into three groups: group A patients treated with CO2 laser(control group), group B treated with injection of optimal amount of extracellular vesicles derived from Wharton jelly mesenchymal cells along with CO2 laser and group C treated with injection of optimal amount of vesicles Wharton jelly mesenchymal cell-derived extracellular alone

Main outcome variables

The amount of melanin in the skin, Examination of skin spots and skin color, Recovery rate, Judgment and satisfaction of patients,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221130056672N6**
Registration date: **2024-02-04, 1402/11/15**
Registration timing: **prospective**

Last update: **2024-02-04, 1402/11/15**
Update count: **0**

Registration date

2024-02-04, 1402/11/15

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

2024-04-03, 1403/01/15

Expected recruitment end date

2024-06-20, 1403/03/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of Safety and Efficacy of Intradermal Injection of Wharton's jelly Mesenchymal Cells Derived Extracellular Vesicles With CO2 Laser in Treatment of Melasma(A randomized controlled intervention study)

Public title
Assessment of the effect of exosomes in the treatment of melasma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 50 years Full satisfaction of the participant in the plan Has melasma (with all three degrees of mild, moderate, severe)
Exclusion criteria:
Previous treatment of melasma Pregnancy and Breastfeeding Active skin infection Use of drugs that can affect bleeding or clotting mechanism Immunosuppression Use of local and systemic steroids Disease systemic diseases (such as high blood pressure ,Diabetes ,heart, kidney and liver diseases) The use of exfoliators 4 weeks before treatment In places where botulinum injection has been done, should not be done due to the possibility of microneedle toxin release. Participation in other clinical trials
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the simple randomization method, the patients who visit Dr. Nilfroshzadeh's skin clinic are divided into 3 groups, so that one envelope is randomly selected for each patient from the number of 30 sealed envelopes. will be Inside each envelope is the letter A, B or C. Group A patients will be treated with CO2 laser(control group),group B will be treated with Injection of optimal amount of extracellular vesicles derived from Wharton's jelly mesenchymal cells along with CO2 laserand group C patients will be treated with Injection of optimal amount of extracellular vesicles derived from Wharton's jelly mesenchymal cells alone
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The people who are treated with CO2 laser are the people who have skin type below 5 and the people whose skin type is 5 and above are excluded from the plan and the laser is not performed for them, CO2 laser with low degree and low density And also the shots are done with less power and with a long distance. Taking into account the possibility of PIH and to prevent this issue, the skin type of the patients is examined first, and then the patients go to the skin center one week before the laser treatment and for them Kligman's combination, which includes 4 grams of hydroquinone, 0.1 grams of dexamethasone and 0.0025 grams of tretinoin, is used. It should be considered that in this plan, our main goal is to investigate the injection of exosomes derived from Wharton jelly mesenchymal cells for melasma disease and the use of CO2 laser with a low level is used for the purpose of the process to increase drug absorption and is used to increase permeability for exosome injection.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Expert Committee on Ethics in Biomedical Research of Tehran University of Medical Sciences
Street address
Deputy Research and Technology Office, 6th Floor , Central Organization of Tehran Universit of Medical Sciences Qods St, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1416613675
Approval date
2023-12-26, 1402/10/05
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.529

Health conditions studied

1

Description of health condition studied
Melasma
ICD-10 code
L81.4
ICD-10 code description
Other melanin hyperpigmentation

Primary outcomes

1

Description
The amount of melanin in the skin
Timepoint
Before starting the treatment and two months after the end of the treatment period (four months after the start of the treatment), biometric examination will be done.
Method of measurement
Biometric device 9MPA-

2

Description
Examination of skin spots and skin color
Timepoint
Before starting the treatment and two months after the end of the treatment period (four months after the start of the treatment), biometric examination will be done.
Method of measurement
Visoface biometric device

Secondary outcomes

1

Description
Recovery rate
Timepoint
before the start of treatment and two months after the end of the treatment period (four months after the start of treatment)
Method of measurement
Photography with ImageJ software

2

Description
Judgment and satisfaction of patients
Timepoint
before the start of treatment and two months after the end of the treatment period (four months after the start of treatment)
Method of measurement
Observation of photographs by two doctors and questionnaire

Intervention groups

1

Description
Control group: CO2 laser is performed as a routine treatment for melasma disease, so group A patients are treated using CO2 laser with a wavelength of 30 j and for 5 minutes in the skin and stem cell center by a specialist doctor and the duration of treatment is 4 sessions with an interval of 1 month.
Category
Treatment - Other

2

Description
Intervention group: Group B is treated by injecting the optimal amount of extracellular vesicles derived from Wharton jelly mesenchymal cells in one-to-one dimensions with a volume of 1 ml in the lesion area along with CO2 laser at the Skin and Hair Research Center. The duration of treatment is 4 sessions with an interval of 1 month.
Category
Treatment - Other

3

Description
Intervention group: Group C is treated by injecting the optimal amount of extracellular vesicles derived from Wharton's jelly mesenchymal cells alone, one to one with a volume of 1 ml in the lesion area in the skin and hair research center. The duration of the treatment is 4 sessions with an interval of 1 month.
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
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
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 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
ethaghiabadi@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
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

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 Address of the workplace: No. 4, 4th floor, Ban Best Maryam, South Kamraniya, Tehran Postal code:19737957511 Phone number:+982126657541 Mobile:+989128057398

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 3 months.

Comments