Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effectiveness of conditioning medium derived from Wharton's jelly tissue along with IPL laser Compared with Wharton jelly tissue-derived extracellular vesicles conditioned with IPL laser In the treatment of rosacea

Protocol summary

Study aim
Investigating the effectiveness of conditioning medium derived from Wharton's jelly tissue along with IPL laser Compared with Wharton jelly tissue-derived extracellular vesicles conditioned with IPL laser In the treatment of rosacea

Design
Phase 1-2 clinical trial, with intervention and control groups, sample size of 30 people, with parallel groups, double-blind, randomized.

Settings and conduct
This project is carried out in the Skin and Stem Cell Research Center of Tehran University of Medical Sciences and is in the field of skin rosacea treatment. It will have 2 intervention groups and a control group. Patients and doctor will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Suffering from rosacea, not receiving other treatments in the last three months, eligible men and women from 18 to 60 years, with severe erythema rosacea. Exclusion criteria: causing severe drug side effects, those who had more than 5 inflammatory lesions on the face.

Intervention groups
Intervention group: After performing the IPL laser, the patients are subjected to the local spray of Wharton's jelly mesenchymal stem cell conditioned medium, 3 times with an interval of 1 month. Intervention group: After IPL laser, patients are subjected to local spray of extracellular vesicles conditioned medium of Wharton's jelly mesenchymal stem cell conditioned medium, 3 times with an interval of 1 month. Control group: patients treated with IPL laser are subjected to local spray of normal saline 3 times with an interval of 1 month.

Main outcome variables
Severity of rosacea lesions based on physician assessment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200127046282N32**
Registration date: **2024-05-13, 1403/02/24**
Registration timing: **retrospective**

Last update: **2024-05-13, 1403/02/24**
Update count: **0**

Registration date
2024-05-13, 1403/02/24

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)

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+98 21 2665 7438

Email address
sonazarebio@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-20, 1402/02/30

Expected recruitment end date
2023-09-06, 1402/06/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effectiveness of conditioning medium derived from Wharton's jelly tissue along with IPL laser Compared with Wharton jelly tissue-derived extracellular vesicles conditioned with IPL laser In the treatment of rosacea

Public title
Investigating the effectiveness of conditioned medium with IPL laser compared to extracellular vesicles with IPL laser in the treatment of rosacea
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from rosacea Not receiving other treatments in the last three months Eligible men and women from 18 to 60 years with severe erythema rosacea based on a patient self-assessment (PSA) score of 4 (severe) and a physician evaluation of erythema (CEA) score of 3 or more have the ability to enter the study
Exclusion criteria:
causing severe drug side effects Those who had more than 5 inflammatory lesions on the face (pointy acne or purulent acne) Specific forms of rosacea (rosacea conglobata, rosacea fulminans, isolated rhinophyma, isolated pastilosis of the chin) They had other facial dermatitis similar to rosacea (such as perioral dermatitis), dimadisidosis, keratinization, seborrheic dermatitis, acute lupus erythematosus, or actinic telangiectasian.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: simple randomization, randomization unit: individual, randomization tool: random number table, total sample size of 30 patients with a history of rosacea in three groups, clinical trial phase: 1-2.
Blinding (investigator's opinion)
Double blinded
Blinding description
Since the appearance of both products are completely similar in terms of color, smell and appearance, patients and doctors do not know about the intervention and control groups, and the study will be considered double-blind.
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.1402.025

Health conditions studied

1

Description of health condition studied
Rosacea
ICD-10 code
L71
ICD-10 code description
Rosacea

Primary outcomes

1

Description
Severity of rosacea lesions based on physician assessment (CEA)
Timepoint
Before treatment and 4 and 8 weeks after
Method of measurement
Physical examination

Secondary outcomes

1

Description
Severity of rosacea lesions based on patient self-assessment (PSA)
Timepoint
Before treatment and 4 and 8 weeks after
Method of measurement
Questionnaire PSA (patient's self-assessment) (evaluating the severity of erythema and redness from the patient's perspective)

Intervention groups

1

Description
Intervention group: After performing the IPL laser, the patients are subjected to the local spray of 5 cc human Wharton's jelly mesenchymal stem cell conditioned medium (Produced by Zist Sakht Bianyan Pars Company - Iran), 3 times with an interval of 1 month.
Category
Treatment - Other

2

Description
Intervention group: After performing IPL laser, patients are subjected to local spray of 5 cc extracellular vesicles conditioned medium of human mesenchymal stem cells of Wharton's jelly (Produced by Zist Sakht Bianyan Pars Company - Iran), 3 times with an interval of 1 month.
Category
Treatment - Other

3

Description
Control group: Patients treated with IPL laser are subjected to a local spray of 5 cc of normal saline, 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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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
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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

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Mohammad Ali Nilforoushzadeh

Position
Professor

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Dermatology

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Person responsible for updating data

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Researcher

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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