

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation therapeutic effect of conditioned medium from 3D culture mesenchymal stem cell spheroids serum for Vitiligo: clinical trial phase 1

Protocol summary

Study aim

Evaluation of topical serum containing mesenchymal stem cell conditioned media on patients with vitiligo

Design

A clinical trial with control groups, parallel assignment, single-blind, simple randomized, phase 1 on 20 patients. To avoid disparity between group sizes, we will use replacement randomization until we achieve a balanced group size

Settings and conduct

The study will be performed at the skin and stem cell research center, Tehran University of Medical Sciences. The intervention area will receive a serum with adipose-derived mesenchymal stem cell conditioned medium and the control group will receive serum without the conditioned medium. The evaluation will be continued twice a day for 45 days.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 18 Years and older, diagnosis of Vitiligo - Generalized vitiligo involving both sides of the body in one or more areas of the body (limbs, trunk, etc.), be able to understand the requirements of the study, and be able to sign an informed consent form, agree to follow the terms of the study and follow-up, lack of corticosteroid-based treatment. Exclusion Criteria: Pregnant females, infection in the donor site, Kubner's evidence in the past, keloidal tendency, patients with focal or segmental vitiligo, patients with vitiligo that affects more than 30% of their body surface, patients who self-reported HIV or hepatitis C, patients self-reported having uncontrolled diabetes mellitus

Intervention groups

Patients are randomly selected. Two active plaques will be selected by a physician on two separate areas of the body. The intervention area will receive a serum containing 3% adipose-derived mesenchymal stem cell conditioned medium and another plaque will receive serum without conditioned medium as a control group.

Main outcome variables

Change to baseline in repigmentation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230324057772N1**

Registration date: **2023-03-29, 1402/01/09**

Registration timing: **prospective**

Last update: **2023-03-29, 1402/01/09**

Update count: **0**

Registration date

2023-03-29, 1402/01/09

Registrant information

Name

Mahsa Mollapour Sisakht

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4462 0324

Email address

mahsamollapour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Evaluation therapeutic effect of conditioned medium from 3D culture mesenchymal stem cell spheroids serum for Vitiligo: clinical trial phase 1
Public title	Stem cell derived topical serum for patients with vitiligo
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: 18 Years and older Diagnosis of Vitiligo - Generalized vitiligo involving both sides of the body in one or more areas of the body (limbs, trunk, etc.) Be able to understand the requirements of the study and be able to sign an informed consent form Agree to follow the terms of the study and follow-up Lack of corticosteroid-based treatment Exclusion criteria: Pregnant females Infection in donor site Kubner's evidence in the past Keloidal tendency Patients with focal or segmental vitiligo are defined as vitiligo that affects only one area of the body on one side of the body Patients with vitiligo that affects more than 30% of their body surface Patients who self-reported HIV or hepatitis C Patients self-reported having uncontrolled diabetes mellitus
Age	No age limit
Gender	Both
Phase	1
Groups that have been masked	Participant
Sample size	Target sample size: 20
Randomization (investigator's opinion)	Randomized
Randomization description	Simple randomization, this method is equivalent to tossing a coin for each subject that enters a trial, such as Heads = Active, Tails = Placebo. Implementation and treatment of assignments are completely unpredictable.
Blinding (investigator's opinion)	Single blinded
Blinding description	Only the researcher doing the study knows which treatment or intervention the participant is receiving until the trial is over.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics committee of Tehran University of Medical Sciences
Street address	6th floor, Qods Ave., Keshavarz Blvd., Tehran University of Medical Sciences, Central building
City	Tehran
Province	Tehran
Postal code	1417755354
Approval date	2023-03-12, 1401/12/21
Ethics committee reference number	IR.TUMS.MEDICINE.REC.1401.855
Health conditions studied	
1	
Description of health condition studied	Vitiligo
ICD-10 code	L80
ICD-10 code description	Vitiligo
Primary outcomes	
1	
Description	Evaluation of skin repigmentation through skin biometry
Timepoint	Before and after of intervention and 3 months after study completion
Method of measurement	Skin Biometry by using MPA9 probe
Secondary outcomes	empty
Intervention groups	
1	
Description	Intervention group: The intervention group will receive a topical serum containing 3% adipose-derived mesenchymal stem cell medium, twice a day for 45 days.
Category	Treatment - Drugs

2

Description

Control group: the group will be received topical serum which is standard care containing: corticosteroid and vitamin D, without adipose derived mesenchymal stem cell conditioned medium, twice a day for 45 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin and stem cell research center

Full name of responsible person

Mahsa Mollapour Sisakht

Street address

Skin & Stem Cell Research Center, Maryam aley,
South kamraneye, Tehran, Iran

City

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Province

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Postal code

1937957511

Phone

+98 21 2220 1710

Email

mahsamolapour@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Street address

Kamraniyeh Ave., Maryam deadend.

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Province

Tehran

Postal code

1937957511

Phone

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Email

dr_nilforoush@yahoo.com

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

Tehran University of Medical Sciences

Full name of responsible person

Mahsa Mollapour Sisakht

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahsa Mollapour Sisakht

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
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Other areas of specialty/work
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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data collected for the primary outcome

When the data will become available and for how long

Data relative to the time after finishing the data collection and 3 months after publication

To whom data/document is available

Available for people working in an academic institution

Under which criteria data/document could be used

There are no specific criteria

From where data/document is obtainable

People can send an email to the responsible person (Dr. Mahsa Mollapour Sisakht) to get more information

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

After requesting the data, you will get an email with the information (Email address: mahsamollapour@gmail.com)

Comments