

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparative evaluation of efficacy of dermabrasion alone, injection of melanocyte suspension and autologous melanocyte suspension transfer in the treatment of vitiligo

Protocol summary

Summary

This study is a randomized clinical trial that its aim is to compare 4 methods of dermabrasion alone, injection of melanocyte suspension (only in Phosphate-buffered saline (PBS)), and combined dermabrasion and melanocyte suspension in PBS or media for the treatment of patients with stable vitiligo. Seventy patients with vitiligo will be enrolled. Inclusion Criteria: Having no treatment within past 6 months and men or women of 11-60 years old. Exclusion Criteria: Vitiligo patients with active or progressive disease within last 12 months. Randomization is done using random number table. In each patient 4 eligible patches will be randomly allocated in 4 above treatment groups (each patch in one group). After skin biopsy from donor site, cell suspension will be prepared in two forms of phosphate-buffered saline (PBS) and patient serum for transfer or injection in recipient site. In recipient site, dermabrasion alone with high-speed dermabrader is used until appearance of the dermo-epidermal junction and pinpoint bleeding. This area is covered with saline soaked gauze, or dermabrasion is done along with the transfer of cell suspension in the base of phosphate-buffered saline (PBS) and patient serum. In injection method, cell suspension is prepared in phosphate-buffered saline (PBS) and is injected in sub cutis area. The improvement rate will be assessed based on percent of repigmentation. Follow up visits will be done during 3 weeks, and 1 and 3 months after the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904081159N6**

Registration date: **2013-08-25, 1392/06/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-25, 1392/06/03

Registrant information

Name

Mohamad Ali Nilforoushzadeh

Name of organization / entity

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

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of efficacy of dermabrasion alone, injection of melanocyte suspension and autologous melanocyte suspension transfer in the treatment of vitiligo

Public title

Comparative evaluation of efficacy of multiple treatments in the treatment of vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1- Having no treatment within past 6 months 2- Men or women of 11-60 years old 3- Have a diagnosis of vitiligo with depigmented patch more than 5 cm despite receiving at least 3 months active treatment 4- Stable vitiligo for at least 1 year 5- No infection at recipient site 6- No history of keloid and or koebner phenomenon 7- No history of active hepatitis the B, C, or AIDS 8- No pregnancy or breast-feeding 9- No active uncontrolled chronic systemic disease Exclusion Criteria: Vitiligo patients with active or progressive disease within last 12 months.

Age

From **11 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not 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

Tehran University of Medical Sciences, Enghelab Street, Tehran, Iran

City

Tehran

Postal code**Approval date**

2012-06-25, 1391/04/05

Ethics committee reference number

57393

Health conditions studied**1****Description of health condition studied**

vitiligo

ICD-10 code

L80

ICD-10 code description

disorder of pigmentation

Primary outcomes**1****Description**

Pigmentation

Timepoint

Before intervention and 1 week, 3 weeks, 1 month and 3 months after transplantation

Method of measurement

Observation, wood lamp, visioface software

Secondary outcomes

empty

Intervention groups**1****Description**

Dermabrasion alone: One time dermabrasion with cone shape head of high speed mini craft dermabrader until appearance of pinpoint bleeding in depigmented patch

Category

Other

2**Description**

Combined dermabrasion and melanocyte suspension in media: One time dermabrasion with cone shape head of high speed mini craft dermabrader until appearance of pinpoint bleeding in depigmented patch and 1 time transfer of 0.4 cc cell suspension in patient serum with replacement of patient serum with any dilution at the end of cell suspension preparation

Category

Other

3**Description**

Injection of melanocyte suspension (only in phosphate-buffered saline (PBS)): One time 0.4 cc sub cutis injection of melanocyte suspension in phosphate-buffered saline with tenfold dilution

Category

Other

4

Description

Combined dermabrasion and melanocyte suspension in PBS: One time dermabrasion with cone shape head of high speed mini craft dermabrader until appearance of pinpoint bleeding in depigmented patch and 1 time transfer of 0.4 cc melanocyte suspension in phosphate-buffered saline with tenfold dilution

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Skin and Stem cell Research Center of Tehran University of Medical Sciences

Full name of responsible person

Fariba Jaffary

Street address

Tehran University of Medical Sciences, Enghelab Street, Tehran, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Vice chancellor for research, Tehran University of Medical Sciences, Enghelab Street, Tehran, Iran

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Skin Diseases and Leishmaniasis Research Center, Isfahan University of Medical Sciences, Isfahan, Ir

Full name of responsible person

Fariba Jaffary

Position

Associate professor

Other areas of specialty/work

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Position

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty