Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative Evaluation of the efficacy of Autologus melanocyte transfer along with PUVA therapy and PUVA therapy alone in vitiligo patients

Protocol summary

Summary

The aim of this treatment was to compare 2 methods of autologous cultured melanocytes transfer along with PUVA therapy with PUVA therapy alone in vitiligo treatment. 20 patients with vitiligo were randomly assigned to receive autologous cultured melanocytes transfer along with PUVA therapy or PUVA therapy alone. Re-pigmentation rate, time of re-pigmentation, and side effects were checked 3 weeks, 3 months, and 6 months after the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706111159N1**
Registration date: **2010-09-07, 1389/06/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-09-07, 1389/06/16

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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+98 21 2220 5158

Email address

sdlrc@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran National Science Foundation

Expected recruitment start date

2007-08-30, 1386/06/08

Expected recruitment end date

2011-08-30, 1390/06/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Evaluation of the efficacy of Autologus melanocyte transfer along with PUVA therapy and PUVA therapy alone in vitiligo patients

Public title

Comparative Evaluation of the efficacy of Autologus melanocyte transfer along with PUVA therapy and PUVA therapy alone in vitiligo patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: no treatment method since prior to 6 months ago, age 11-60, treatment history for 3 months
Exclusion criteria: pregnancy, breast feeding, depigmented patch >5 squared cm, active vitiligo, infection on treated site, cloid history, Cobner reaction

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: **20**

Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Hezar jarib blv., Azadi sq., Isfahan
City
Isfahan
Postal code
Approval date
2010-06-12, 1389/03/22
Ethics committee reference number
29033

Health conditions studied

1

Description of health condition studied
vitiligo
ICD-10 code
L80
ICD-10 code description
disorders of pigmentation

Primary outcomes

1

Description
repigmentation rate
Timepoint
3 weeks, 3 months, 6 months after treatment
Method of measurement
perfect >90%, good 65-89%, moderate 25-64%, fair <25%

2

Description
side effects
Timepoint
3 weeks, 3 months, 6 months after treatment
Method of measurement
observation

Secondary outcomes

empty

Intervention groups

1

Description
autologous melanocyte culture along with puva therapy
Category
Treatment - Surgery

2

Description
puva therapy alone
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Skin Disease and Leishmaniasis Research Center
Full name of responsible person
Mohammad Ali Nilforoushzadeh M.D
Street address
Third floor, Sedighe Tahereh building, Khorram st., Jomhoori sq., Isfahan
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran National Science Foundation
Full name of responsible person
Dr mahmood ahmadinejad
Street address
No 1, 5th street, Jalale al Ahmad cross, North Kargar Ave.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran National Science Foundation
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 Disease and Leishmaniasis Research Center, Isfahan University of Medical Sciences,

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Associate Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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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