

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 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)

###### Phone

+98 21 2220 5158

###### Email address

sdIrc@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, clonid 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

#### Street address

Third floor, Sedighe Tahereh building, Khorram st.,  
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sdllrc@mui.ac.ir

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Skin Disease and Leishmaniasis Research Center

#### Full name of responsible person

Mohammad Ali Nilforoushzadeh

#### Position

Associate professor

#### Other areas of specialty/work

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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*