

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of intra-epidermal injection of autologous epidermal cell suspension effect on repigmentation of patches in vitiligo patients

#### Protocol summary

##### Summary

Objectives: Evaluation of intra-epidermal injection of autologous epidermal cell suspension effect on repigmentation of patches in vitiligo patients Design: open-label, non-randomized phase III, single center clinical trial Participants: Age of at least 12 years old; Stability of vitiligo at least for one year; Exclusion Criteria: Pregnancy or lactation; active underline disease; Keloid tendency Primary Outcome: repigmentation percent Secondary outcome: Safety of the intervention Sample size: 300 patients Intervention: A shaved skin biopsy specimen (one fifth the recipient patch surface area) is taken from the patient's normally pigmented area on the gluteal region by a hand dermatome, under local anesthesia (lidocaine hydrochloride 20 mg/ml). After dissociating epidermal cells, the Well-dispersed cell suspension is aspirated into 1 ml syringes and injected directly in epidermis.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201508201031N16**  
Registration date: **2016-05-15, 1395/02/26**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-15, 1395/02/26

##### Registrant information

###### Name

Nasser Aghdami

###### Name of organization / entity

Royan Institute

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2356 2000

###### Email address

nasser.aghdami@royaninstitute.org

##### Recruitment status

###### Recruitment complete

##### Funding source

Department of Regenerative Biomedicine, Cell Science Research Center, Royan Institute for Stem Cell Biology and Technology

##### Expected recruitment start date

2009-01-19, 1387/10/30

##### Expected recruitment end date

2015-03-18, 1393/12/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of intra-epidermal injection of autologous epidermal cell suspension effect on repigmentation of patches in vitiligo patients

##### Public title

Vitiligo

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: Age over 12 years; Stable form of vitiligo (no increase in the size of the lesion for at least one year); No use of immunosuppressive and cytotoxic drugs at least for past 6 months Exclusion Criteria: Pregnancy or lactating; Patients with active disease; Infection at the recipient/donor site; Evidence of köebner in the past; Keloidal tendencies; underline chronic disease

## Age

From **12 years** old to **75 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **300**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

No other feature

## Secondary Ids

### 1

#### Registry name

ClinicalTrials.gov

#### Secondary trial Id

NCT00631865

#### Registration date

2008-03-03, 1386/12/13

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Royan infertility institute

##### Street address

Eastern Hafez St,Northern Banihashem St, 45 m  
Resalat highway

##### City

Tehran

##### Postal code

#### Approval date

2007-08-21, 1386/05/30

#### Ethics committee reference number

86/530/پ

## Health conditions studied

### 1

#### Description of health condition studied

Vitiligo

#### ICD-10 code

L80

#### ICD-10 code description

Vitiligo

## Primary outcomes

### 1

#### Description

Percentage of repigmentation

#### Timepoint

3,6 and 12 months after transplantation

#### Method of measurement

Physician assessment

## Secondary outcomes

### 1

#### Description

Safety of the intervention

#### Timepoint

3,6 and 12 months after transplantation

#### Method of measurement

Patients history

## Intervention groups

### 1

#### Description

Intervention: Autologous Transplantation of epidermal cell suspension

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Skin Clinic of Royan Institute

##### Full name of responsible person

Mahshid Ghasemi

##### Street address

Eastern Hafez St,Northern Banihashem St, 45 m  
Resalat highway

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Royan Institute

##### Full name of responsible person

Hamid Gourabi

##### Street address

Eastern Hafez St,Northern Banihashem St, 45 m  
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**City**  
Tehran

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**  
Royan Institute

**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**  
Royan Institute

**Full name of responsible person**  
Mahshid Ghasemi

**Position**  
M.D/ Researcher

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Hoda Madani

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## 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*