Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Parcipitants: Age of at least 12 years old; Stablity of vitiligo at least for one year; Exclusion Criteria: Pregnancy or lactation; active underline disease; Kelloid 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 Resalat highway

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
Street address
Eastern Hafez St,Northern Banihashem St, 45 m Resalat highway
City
Tehran
Postal code
Phone
+98 21 2251 8388
Fax
Email
mdmg83@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Royan Institute
Full name of responsible person
Nasser Aghdami
Position
M.D,Ph.D
Other areas of specialty/work
Street address
Eastern Hafez St,Northern Banihashem St, 45 m Resalat highway
City
Tehran
Postal code
Phone
+98 21 2251 8388
Fax
Email
nasser.aghdami@royaninstitute.org
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Royan Institute
Full name of responsible person
Hoda Madani
Position
M.D/ Researcher
Other areas of specialty/work
Street address
Eastern Hafez St,Northern Banihashem St, 45 m Resalat highway
City
Tehran
Postal code
Phone
+98 21 2251 8388
Fax
Email
hoda62_m@yahoo.com
Web page address

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