Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of autologous non-cultured and non-trypsinised melanocytes and keratinocytes grafting in treatment of refractory vitiligo

Protocol summary

Study aim

To assess the efficacy of autologous, non-cultured and non-trypsinized melanocyte transplantation in treatment of stable vitiligo

Design

This phase 3 study is performed in 93 vitiligenous lesions at single center in vitiligo patients who refer to single center of Haj daie dermatology clinic in Kermanshah city. Information about this procedure is given to the patients and after obtaining consent enroll in study.

Settings and conduct

Vitiligo is a common dermatology disorder that usually unresponsive to medical therapy and associated with unpleasant appearance, familial problems and neuro-psychiatric disorder.The donor site containing normal pigmentation such as buttock and thigh area is selected. After local anesthesia, firstly the epidermis is shaved using a curretage number 2 until point bleeding appears as a marker of the epidermis and dermis junction, later he harvested material is mixed with some hyaluronic acid gel in a sterile container and finally this suspension transplanted in recipient denuded sites. This site is dressed with semi-permeable dressing. The patient is evaluated at the first and third week and then monthly. The rate of re-pigmentation and possible complications are recorded.

Participants/Inclusion and exclusion criteria

Patients who clinically confirmed stable vitiligo are subjected to treatment.Pregnant and breast feeding women, patients with cardio-vascular and repair disorder, unstable and universal vitiligo rule out from study.

Intervention groups

Because of absence of melanocyte reservoir in vitiligenous lesions most of vitiligo unresponsive to ordinary treatment and phototherapy. Autologous, non-cultured and non-trypsinized melanocyte transplantation is a safe and less aggressive procedure that can be a appropriate method for treatment of refractory vitiligo.

Main outcome variables

The rate of re-pigmentation in treated area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110507006403N9**
Registration date: **2020-03-16, 1398/12/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-16, 1398/12/26**
Update count: **0**

Registration date

2020-03-16, 1398/12/26

Registrant information

Name
Hossein Kavoussi
Name of organization / entity
Kermanshah University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 83 1837 5424
Email address
hkawosi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-19, 1398/11/30

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of autologous non-cultured and non-trypsinised melanocytes and keratinocytes grafting in treatment of refractory vitiligo

Public title

Efficacy of autologous and non-processed melanocyte grafting in treatment of vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinically documented vitiligenous lesions

Exclusion criteria:

Unstable vitiligo Pregnancy Breast feeding Generalized vitiligo Patients recently subject to phototherapy and drugs used for vitiligo Cardio-vascular patients Patients with repair disorder

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **5**

Patients usually have more than one lesion.

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

hajdaei clinic

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.KUMS.REC.1398.975

2

Ethics committee

Name of ethics committee

ethicts committee of medical univercity of kermanshah

Street address

mostafa emami

City

kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

ir.kums.rec.1398.975

3

Ethics committee

Name of ethics committee

ethics committee of kermanshah univercity medical science

Street address

mostafa emami Ave., kermanshah city,

City

kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

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Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description
Re-pigmentation
Timepoint
The first and third week and then every month for up to 4 months
Method of measurement
Area measurement with software

Secondary outcomes

empty

Intervention groups

1

Description
The epidermis is shaved from the lower limb as donor site, which has normal pigment with a disposable and sharp curettage device. The harvested materials is mixed with hyaluronic acid gel. The vitiligo skin patches as recipient site, also is shaved with curettage. Later the harvested suspension is transplanted in the recipient site. The patient is evaluated at the first and third week and then monthly.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Haj daie dermatology clinic
Full name of responsible person
Hossein Kavoussi
Street address
No.1, Haj daie clinic, Golestan Blvd
City
Kermanshah
Province
Kermanshah
Postal code
6714647934
Phone
+98 83 3845 3486
Email
hkawosi@kums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
Street address
No 2 bulding, Shahid Beheshty Blvd
City
Kermanshqah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3837 0541
Email
farid_n32@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Fatemeh Ahmad Aghaei
Position
Dermatology residency
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
No.1, Haj daie dermatology clinic, Golestan Blvds
City
Kermanshah
Province
Kermanshah
Postal code
6714647934
Phone
+98 83 3845 3486
Email
fatemehahmadaghaei@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Ali Ebrahimi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
No. 1, Haj daie dermatology clinic, Golestan Blvd
City
Kermanshah
Province
Kermanshah
Postal code
6714647934
Phone
+98 83 3845 3486
Email
Ebrahimider@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Reza Kavoussi
Position
General practitioner
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
No. 1, Haj daie drmatology clinic, Golestan Blvd
City
Kermanshah
Province
Kermanshah
Postal code
6714647934
Phone
+98 83 3845 3486
Email
reza.kavoussi73@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available