

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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 vitiliginous 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 vitiliginous 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 vitiliginous 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
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Approval date
2020-01-14, 1398/10/24
Ethics committee reference number
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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
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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

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Postal code

6714647934

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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

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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

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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

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Other areas of specialty/work

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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

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