Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Investigating the efficacy of actinidin isolated epidermis grafting in repigmentation of vitiligo patients

Protocol summary

Study aim
Determining the efficacy of Actinidin-separated epidermis grafting in repigmentation of vitiligo patients

Design
Clinical trial with parallel groups, without blinding, randomized, on 96 patients.

Settings and conduct
Vitiligo patients are separated from the epidermis by actinidin at the Haj Dayi Clinic and transplanted to the depigmented area, and the transplant recipient is examined for repigmentation after two weeks, two months, and six months.

Participants/Inclusion and exclusion criteria
Age 13 to 60 years, the presence of at least two affected areas, vitiligo vulgaris or stable segmental vitiligo, lack of adequate response to drug treatments and phototherapy, the degree of involvement is less than 30% of the total body surface, and lacks the exclusion criteria, which include: adequate response to drug and phototherapy treatments, history of cardiovascular disease, age under 13 and over 60, pregnancy and breastfeeding, positive history of Kobner Phenomenon, presence of hypertrophic or keloid scars, and unstable vitiligo in the past 1 year, the presence of active infection in the place

Intervention groups
The intervention group of vitiligo vulgaris or persistent segmental vitiligo patients with at least 13 years of age and lack of adequate response to drug and phototherapy treatments with involvement of less than 30% of the total body surface is first injected with local anesthesia at the receptor site and then isolated by skin dermatome. can be After separating the epidermis from the dermis by actinidin and preparing the recipient site with a laser device, the epidermis is placed in place and bandaged.

Main outcome variables
Primary outcomes are described as poor, moderate, good, and excellent repigmentation.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090515001906N13**
Registration date: **2023-12-02, 1402/09/11**
Registration timing: **retrospective**

Last update: **2023-12-02, 1402/09/11**
Update count: **0**

Registration date
2023-12-02, 1402/09/11

Registrant information

Name
Ali Ebrahimi

Name of organization / entity
Kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 83 1823 3862

Email address
aebrahimi@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
2022-09-23, 1401/07/01

Actual recruitment end date
2023-03-20, 1401/12/29

Trial completion date
2023-10-22, 1402/07/30

Scientific title
Investigating the efficacy of actinidin isolated epidermis grafting in repigmentation of vitiligo patients

Public title
Use of actinidin in skin grafting

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 13 to 60 years The presence of at least two affected areas Persistent vitiligo vulgaris or segmental vitiligo (there has been no increase in the size of depigmented patches for at least one year) Lack of appropriate response to drug and phototherapy treatments The rate of involvement is less than 30% of the total body surface

Exclusion criteria:
Appropriate response to drug and phototherapy treatments History of cardiovascular disease Age under 13 years and over 60 years Pregnancy and breastfeeding Positive history of Kobner Phenomenon Presence of hypertrophic or keloid scars Unstable vitiligo during the past 1 year Presence of active infection at the site

Age
From **13 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**
Actual sample size reached: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Central randomization: In this method, a random sequence is provided to a specific center, and the researcher is contacted based on the order in which the research participants (patients) entered the research area (Haj Dayi Clinic) and the participant is randomly assigned to one of the two special groups. Among the methods of communication, we can refer to telephone, face-to-face, etc., in this research, the face-to-face method is used.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Kermanshah Medical School

Street address
No. 1 , Medical School., Parastar Blvd

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2023-05-28, 1402/03/07

Ethics committee reference number
IR.KUMS.MED.REC.1402.112

Health conditions studied

1

Description of health condition studied
Vitiligo

ICD-10 code
L80

ICD-10 code description
Vitiligo

Primary outcomes

1

Description
The degree of repigmentation is described as poor, moderate, good and excellent

Timepoint
The beginning of the study, the second week, the second month and the sixth month

Method of measurement
Taking photos with Finepix camera and comparing photos at set times

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For each patient, after local anesthesia in the donor site, the epidermis is separated with a thin layer of dermis by a dermatome. In the next step, the separated skin is placed in actinidin enzyme with a volume of 5 mg per liter and a volume of 2 ml and placed in an incubator at a temperature of 37 degrees for 10 minutes. Epidermis separated by actinidin is placed in contact with the dermis of the receiving area and nano-dressed.

Category
Treatment - Surgery

2

Description
intervention group: for each patient, a suction-blister device is placed for one to two hours to separate the epidermis in the donor site, and then the separated epidermis is transplanted to the recipient site, whose epidermis has already been removed with a laser device.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Haj Dayi Clinic
Full name of responsible person
Ali Ebrahimi
Street address
Haj Dayi Clinic., Golestan Ave., Golesorkh Blvd.
City
Kermanshah
Province
Kermanshah
Postal code
6717735838
Phone
+98 83 3835 9054
Email
aebrahimi@kums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Cirus Jalili
Street address
No. 2 , University of Medical Sciences., SHahid Beheshti Blvd
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3838 4185
Fax
+98 83 3837 0541
Email
cjalili@kums.ac.ir
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
Marzieh Fathi
Position
Dermatology resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Golestan, Gol e Sorkh Blvd, Haj Dayi Clinic
City
Kermanshah
Province
Kermanshah
Postal code
6717735838
Phone
+98 83 3835 9054
Email
rasad313313@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Ali Ebrahimi
Position
Member of Scientific Board of Kermanshah University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Golestan, Gol e Sorkh Blvd, Haj Dayi Clinic
City
Kermanshah

Province
Kermanshah
Postal code
6717735838
Phone
+98 83 3835 9054
Email
aebrahimi@kums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Ali Ebrahimi
Position
Member of Scientific Board of Kermanshah University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
School of Medicine, parastar boulvarde
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 4618
Email
aebrahimi@kums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The main outcomes of the study will be shared
When the data will become available and for how long
2 months
To whom data/document is available
If requested, results will be made available to other academic researchers
Under which criteria data/document could be used
Collected data is confidential and will not be shared with anyone else
From where data/document is obtainable
To receive the documentation, email send for update manager
What processes are involved for a request to access data/document
In a 15-day period, the documents will be sent e-mail
Comments