Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of the efficacy of nano dressing in comparison common dressing after grafting of epidermal suspension containing melanocyte and keratinocyte in treatment of resistant vitiligo

Protocol summary

Study aim
Study of the efficacy of nano dressing in comparison common dressing after grafting of epidermal suspension containing melanocyte and keratinocyte in treatment of refractory vitiligo

Design
This study is a one-blinded clinical trial. The study population will be all patients referring to HajiDay Clinic in Kermanshah. 130 eligible patients will be selected conveniently and randomly assigned to intervention and control groups.

Settings and conduct
This study, which will be conducted at Taleghani Hospital of Kermanshah, is one-blind one that the researcher is unaware of the intervention method which is the type of dressing. After the intervention, the radiographs will be taken before and after the procedure and during the Follow-up Period.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 11 and 60; Patients with vitiligo who have not been treated with corticosteroids or PUVA for at least 12 weeks; No active vitiligo; The absence of the Kubner phenomenon in the past Exclusion criteria: Fertile and lactating women; Colloid history

Intervention groups
The intervention group will be dressed for one week with biodegradable and biodegradable nano dressing prepared by electrospinning. The control group will be dressed with conventional tetracycline ointment for one week

Main outcome variables
Wound healing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N133**
Registration date: **2019-12-25, 1398/10/04**
Registration timing: **prospective**

Last update: **2019-12-25, 1398/10/04**
Update count: **0**

Registration date
2019-12-25, 1398/10/04

Registrant information

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kermanshah University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-10, 1398/10/20

Expected recruitment end date
2020-03-10, 1398/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the efficacy of nano dressing in comparison

common dressing after grafting of epidermal suspension containing melanocyte and keratinocyte in treatment of resistant vitiligo

Public title
Study of the efficacy of nano dressing in comparison common dressing treatment of vitiligo
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 11 and 60 Patients with vitiligo who have not been treated with corticosteroids or PUVA for at least 12 weeks No active vitiligo The absence of the Kubner phenomenon in the past
Exclusion criteria:
Fertile and lactating women Colloid history
Age
From **11 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Investigator

Sample size
Target sample size: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomly by tossing coin
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the researcher is blinded to the intervention, which is a type of dressing and does not know which type of dressing will be used to treat them.
Placebo
Not used
Assignment
Parallel
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
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
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Province
Kermanshah
Postal code
6715847141
Approval date
2019-09-17, 1398/06/26
Ethics committee reference number
ir.kums.rec.1398.674

Health conditions studied

1

Description of health condition studied
Vitiligo
ICD-10 code
L80
ICD-10 code description
Vitiligo

Primary outcomes

1

Description
Wound healing
Timepoint
The first month is weekly and then monthly for up to 6 months
Method of measurement
Medical Imaging

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will be dressed for one week with biodegradable and biodegradable nano dressing prepared by electrospinning.
Category
Treatment - Drugs

2

Description
The control group will be dressed with conventional tetracycline ointment for one week
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan, Haji Dai Clinic

Full name of responsible person
Hamid Eftekharipirouz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
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Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
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fnajafi@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
Hamid Eftekharipour
Position
Resident in Dermatology
Latest degree
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Person responsible for updating data

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Resident in Dermatology
Latest degree
Medical doctor
Other areas of specialty/work
Skin

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
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