

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

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
Kermanshah

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 Eftekharipour

Street address

Golestan, Haji Dai Clinic

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3835 9054

Email

Hamideftekharipour@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for
Research Affairs, Kermanshah University of Medical
Sciences

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+98 83 3836 0014

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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

Medical doctor

Other areas of specialty/work

Skin

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Golestan, Haji Dai Clinic

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Ali Ebrahimi

Position

Member of Kermanshah University of Medical
Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Beautiful skin and hair

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Person responsible for updating data

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Hamid Eftekharipour

Position

Resident in Dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Skin

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Email

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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