

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the additional effect of 15% TCA peel on response to phototherapy of patients with acral vitiligo

Protocol summary

Study aim

Evaluation of the additional effect of 15% TCA peel on response to phototherapy of patients with acral vitiligo

Design

Clinical trial with parallel groups, randomized and single blind, conducted on 40 patients

Settings and conduct

This study will be conducted on 40 patients with acral vitiligo referring to Imam Reza Hospital. Patients are randomly divided into two groups. Size of vitiligo lesions are measured using photography. In the intervention group, for one side of the patient's limb, treatment with 15% TCA peel will be performed once a week for 1 month. Then, after 10 to 15 days, phototherapy will begin twice a week for 6 months, preferably using PUVA bath therapy. For the other side of the patient's limb as the control group, only phototherapy will be performed. At the end of the study, rate of repigmentation of patients' limbs will be compared before and after intervention and also between opposite limbs based on the photos taken. In this single blind study, only outcome assessors are unaware of the type of groupings.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with acral vitiligo; age is over 12 years. Exclusion criteria: patients with a history of Koebner phenomenon; patients with a history of keloids; pregnancy; photosensitivity

Intervention groups

In the intervention group, for one side of the patient's limbs, treatment with 15% TCA peel will be performed once a week for 1 month. Then, after 10 to 15 days, phototherapy will begin twice a week for 6 months, preferably using PUVA bath therapy. For the opposing side of the patient's limbs as the control group, only phototherapy will be performed.

Main outcome variables

Size of vitiligo lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211024052859N1**

Registration date: **2022-01-19, 1400/10/29**

Registration timing: **prospective**

Last update: **2022-01-19, 1400/10/29**

Update count: **0**

Registration date

2022-01-19, 1400/10/29

Registrant information

Name

Yasaman Rastegar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3649 0953

Email address

rastegary971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-04, 1400/11/15

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the additional effect of 15% TCA peel on response to phototherapy of patients with acral vitiligo

Public title

The effect of 15% TCA peel on phototherapy of patients with acral vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with acral vitiligo Age is over 12 years

Exclusion criteria:

Patients with a history of Koebner phenomenon Patients with a history of keloids Pregnancy Photosensitivity

Age

From **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The envelopes will be prepared by one of the members of the research team and the random numbers generated by the "www.randomization.com" website will be printed and placed in each envelope. In this website, the number of participants along with the number of groups are entered. Then for each group, a number of codes will be generated randomly. The envelopes are sealed and their contents are not visible from outside. At first, purpose of the study is explained for each participants and after filling out the consent form, each participant selects an envelope and opens it and based on the type of intervention, receives phototherapy and 15% TCA peel for organs of one side as intervention and only phototherapy for the other side of body as control group. Randomization only takes place to select the right or left limb.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study only outcome assessors, when evaluating the patients, will be unaware of how patients are grouped and which treatment they receive. No placebo drug will be used in this study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2021-04-13, 1400/01/24

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.276

Health conditions studied**1****Description of health condition studied**

acral vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes**1****Description**

Size of vitiligo lesions

Timepoint

At the beginning of the study and after 6 months of phototherapy

Method of measurement

Images taken before and after the intervention are compared between the two groups after 6 months of phototherapy by two physicians outside the study based on the rate of repigmentation. The ideal response is above 75% repigmentation.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In this group, for one side of the patient's body (either the left or the right limb) which will be determined after randomization, treatment with 15% TCA peel will be performed once a week for 1 month.

Then, after 10 to 15 days, phototherapy will begin twice a week for 6 months, preferably using PUVA bath therapy.

Category

Treatment - Drugs

2

Description

Control group: In this group, for the limb opposing the one in the intervention group, only phototherapy will begin twice a week for 6 months, preferably using PUVA bath therapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Yalda Nahidy

Street address

Imam Reza Hospital, next to Imam Reza square, Ibne Sina street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Yasaman Rastegar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Professor

Latest degree

Specialist

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data can be accessible through an email to the corresponding author.

Under which criteria data/document could be used

Data will be available for researchers in universities and other scientific institutes.

From where data/document is obtainable

After sending a request email to the corresponding author, data will be sent in 1 month.

What processes are involved for a request to access data/document

Carrying out analysis on data is permitted.

Comments