Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the simultaneous effect of all three therapeutic methods of Fire needle, Moxibustion, and auriculotherapy with and without light therapy with narrow band ultraviolet rays (NB-UVB) in vitiligo patients

Protocol summary

Study aim

Comparison of therapeutic effect of warm acupuncture, massage and auriculotherapy with and without light therapy in vitiligo patients

Design

The trial has two groups of 5 people, including the first group (control group), treatment without light therapy, treatment with warm acupuncture, massage and auriculotherapy, and the second group, in addition to light therapy, treatment with warm acupuncture, massage and auriculotherapy, and statistical methods used to compare groups in terms of primary and secondary outcomes, methods used in additional analyses, such as subgroup analyzes and adjusted analyses.)

Settings and conduct

This study was conducted at the Molecular Dermatology Research Center affiliated to Shiraz University of Medical Sciences and the Dermatology Clinic of Faqihi Hospital in Shiraz and as an experiment in the form of a single-blind randomized controlled clinical trial, which was randomized based on the permutation table. The treatments were given twice in The week is done for three months and the patients are followed up for 6 months.

Participants/Inclusion and exclusion criteria

Patients, regardless of ethnicity and disease duration, at least 18 years old and without serious systemic disease, will participate in this study after a doctor's visit, eligibility and signed consent form. Pregnant and lactating mothers and special patients will not participate in this study.

Intervention groups

Treatment with hot acupuncture, massage and auriculotherapy with and without light therapy

Main outcome variables

The recovery rate of lesions of vitiligo patients The percentage of vitiligo involvement is calculated per hand unit.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110731007160N9**
Registration date: **2023-08-07, 1402/05/16**
Registration timing: **prospective**

Last update: **2023-08-07, 1402/05/16**
Update count: **0**

Registration date

2023-08-07, 1402/05/16

Registrant information

Name

Nasrin Hamidizadeh

Name of organization / entity

Molecular Dermatology Research Center, Shiraz University of Medical Sciences, Shiraz, Iran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-11, 1402/05/20

Expected recruitment end date

2023-10-21, 1402/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the simultaneous effect of all three therapeutic methods of Fire needle, Moxibustion, and auriculotherapy with and without light therapy with narrow band ultraviolet rays (NB-UVB) in vitiligo patients

Public title

Comparison of the therapeutic effect of fire-needling, moxibustion and auriculotherapy in vitiligo patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Regardless of ethnicity and disease duration, patients at least 18 years of age and without severe systemic disease will participate in this study after a physician visit, eligibility, and signing of an informed consent form.

Exclusion criteria:

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd, Shiraz

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2023-01-10, 1401/10/20

Ethics committee reference number

IR.SUMS.REC.1401.641

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Pigmentation in vitiligo lesions

Timepoint

Pigmentation in vitiligo lesions

Method of measurement

Vitiligo Area Scoring Index (VASI)

Secondary outcomes

1

Description

Intervention group: Patients are divided into two groups of 5 people who will participate in each group. In addition to light therapy, the intervention group is also treated with hot acupuncture, massage and auriculotherapy.

Timepoint

Treatment will be given twice a week for three months, and patients will be followed up for six months.

Method of measurement

Vitiligo Area Scoring Index (VASI)

Intervention groups

1

Description

Intervention group: Patients are divided into two groups of 5 people. In the first intervention group, in addition to light therapy, treatment with hot acupuncture, massage, and auriculotherapy is also performed.

Category

Treatment - Other

2

Description
Intervention group: Patients are divided into two groups of 5 people. The second intervention group without light therapy, the treatment is done only with the help of hot acupuncture, massage and auriculotherapy.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Molecular Dermatology Research Center

Full name of responsible person
Dr.Nasrin Hamidizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Dr.Nasrin Hamidizadeh

Position
Manager of Research Center

Latest degree
Ph.D.

Other areas of specialty/work
Immunology

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Person responsible for scientific inquiries

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Name of organization / entity
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Position
Director

Latest degree
Ph.D.

Other areas of specialty/work
Immunology

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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
Presenting the results of the VASI index regarding the percentage of improvement
When the data will become available and for how long
Immediately after the publication of the article
To whom data/document is available
Researchers
Under which criteria data/document could be used
Send researchers' requests via email and make a commitment to applicants to protect the data
From where data/document is obtainable
Sending researchers' requests via e-mail to the e-mail address of the executor and in charge of the project, Dr. Nasrin Hamidizadeh. n.hamidizadeh.mdrc@gmail.com
What processes are involved for a request to access data/document
The applicant researcher should send his request to the email address of the executor of the project, Dr. Nasrin Hamidizadeh (n.hamidizadeh.mdrc@gmail.com). Within one week after evaluation, the data will be sent to the applicant via email, along with making a commitment.
Comments