

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Assessing the effect of energetic water on the response of lesions in vitiligo patients treating with PUVA (a randomized clinical trial study

Protocol summary

Study aim

The effect of energy water on the healing of skin lesions in patients with vitiligo

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 50 patients. To prepare random blocks with variable sizes from <https://www.sealedenvelope.com/simple-randomiser/v1/lists> is used.

Settings and conduct

50 new patients are randomly selected. after obtaining informed consent are placed in two groups of intervention and control. Both receive PUVA 2 sessions per week. simple and energetic water are coded by the supplier And it's divided randomly between two groups .both consume orally 1liter per day from the first day of phototherapy to the end of the third month. Demographics, The extent and severity of vitiligo in the two groups at the beginning, sixth week and end of the twelfth week are measured by VASI score and the response of the two groups is compared. In this study, the analyzer and participants are unaware of the type of water of each code.

Participants/Inclusion and exclusion criteria

Inclusion criteria: New patients with vitiligo who undergo puva phototherapy and at the same time do not receive any medications for the treatment of vitiligo will be included in the study after obtaining informed consent. exclusion criteria: Patients who are not undergoing phototherapy or are simultaneously using another drug to treat vitiligo or who are not satisfied with attending the study.

Intervention groups

In the intervention group, patients consume 1 liter per day of cosmic energetic water for 3 months, in addition to phototherapy. In the control group, in addition to phototherapy, they receive one liter of regular water per day in similar containers.

Main outcome variables

1. The speed of treatment of vitiligo 2. Success rate in the treatment of vitiligo 3. The amount of time spent treating vitiligo 4. The amount of money spent for the treatment of vitiligo

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211219053455N1**

Registration date: **2022-01-03, 1400/10/13**

Registration timing: **prospective**

Last update: **2022-01-03, 1400/10/13**

Update count: **0**

Registration date

2022-01-03, 1400/10/13

Registrant information

Name

Masoud Khoshraftar Roudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3840 8413

Email address

khoshraftarm991@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2023-04-04, 1402/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of energetic water on the response of lesions in vitiligo patients treating with PUVA (a randomized clinical trial study

Public title

Assessing the effect of cosmic energetic water on vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

New patients with vitiligo who receive light therapy with PUVA and at the same time do not receive another drug to treat vitiligo enter the study after obtaining informed consent

Exclusion criteria:

Patients who are treated with other drugs for vitiligo in addition to phototherapy or are unwilling to continue treatment and intervention are excluded from the intervention.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocking method: to prepare random blocks with variable sizes from the site sealedenvelope.com/simple-randomiser/v1/lists is used. The contents of each block are sealed in a closed envelope and when patients refer, one of the blocks is randomly selected and placed in one of the study arms, depending on the content of the individual. Similarly, after the completion of the first block, the second block is randomly selected and this continues until the last block and the allocation of the last person to the study arms. It is established between groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The analyst and participant will be unaware of the intervention and control groups. Both types of energy water and regular drinking water are similar in color, smell and taste and are placed in two containers A and B, which will be watered to 25 participants from container A and 25 others from container B.

Placebo

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

4th floor, No164 ,Pars 22, Kuhsangi

City

Mashhad

Province

Razavi Khorasan

Postal code

9175734719

Approval date

2021-12-04, 1400/09/13

Ethics committee reference number

IR.MUMS.REC.1400.281

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

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

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

Healing and preventing the progression of skin lesions in patients with vitiligo

Timepoint

Before the intervention, 45 and 90 days after the start of energetic water consumption

Method of measurement

VASI score index

Secondary outcomes

empty

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

Intervention group: Daily oral consumption of one liter of energetic water produced by a pyramid resonator

Category
Treatment - Drugs

2

Description
Control group: Daily oral consumption of one liter of ordinary drinking water

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Masoud Khoshraftar Roudi

Street address
Daneshgah Ave, Shariati Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3854 3031

Email
Khoshraftarm991@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Research Assistant

Street address
Ghoreishi Building, Daneshgah Ave, Shariati Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Phone
+98 51 3841 2081

Email
Presidentoffice@mums.ac.ir

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
Masoud Khoshraftar Roudi

Position
Dermatology Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

Street address
4th floor, No 164, Pars22, Kuhsangi

City
Mashhad

Province
Razavi Khorasan

Postal code
9175734719

Phone
+98 51 3840 8413

Email
Khoshraftarm991@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Masoud Khoshraftar Roudi

Position
Dermatology Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

Street address
4th floor, No162, Pars22, Kuhsangi

City
Mashhad

Province
Razavi Khorasan

Postal code
9175734719

Phone

+98 51 3840 8413

Email

Khoshraftarm991@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Masoud Khoshraftar Roudi

Position

Dermatology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

4th floor, No 164, Pars22, Kuhsangi

City

Mashhad

Province

Razavi Khorasan

Postal code

9175734719

Phone

+98 51 3840 8413

Email

khoshraftarm991@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available