

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Effectiveness of safflower honey-based topical product with tacrolimus on improvement of symptoms (whiteness size and color) in vitiligo patients

Protocol summary

Study aim

1- Determining and comparing the size of skin spots in vitiligo patients before and after the intervention in two groups receiving safflower honey-based product and tacrolimus. 2- Determining and comparing the color of skin spots in vitiligo patients before and after the intervention in two groups receiving safflower honey-based product and tacrolimus. 3- - Evaluation and comparison of vitiligo quality of life before and after intervention in two groups receiving safflower honey-based product and tacrolimus.

Design

A controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 42 patients. For randomization, randomization is used by software.

Settings and conduct

The place where the study was conducted was Razi Dermatology Hospital in Tehran on patients with vitiligo and it was blinded in three ways.

Participants/Inclusion and exclusion criteria

Criteria for entering the project: 1- Willingness to participate and sign the informed consent form 2- Age 60-12 years 3- Having clear vitiligo lesions with the approval of a dermatologist 4- Involvement of less than 10% of the body surface Criteria for not entering the plan: 1- pregnancy or breastfeeding 2- local treatment of vitiligo in the last 4 weeks or systemic treatment or phototherapy in the last 12 weeks 3- progress in the last 6 weeks 4- serious underlying disease or use of immunosuppressive drugs

Intervention groups

Local administration of safflower honey-based product or tacrolimus

Main outcome variables

Reducing the size and increasing the color of vitiligo lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221226056928N1**

Registration date: **2023-01-23, 1401/11/03**

Registration timing: **prospective**

Last update: **2023-01-23, 1401/11/03**

Update count: **0**

Registration date

2023-01-23, 1401/11/03

Registrant information

Name

Mohammadreza Najjarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 7773 4834

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2024-05-20, 1403/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of safflower honey-based topical product with tacrolimus on improvement of symptoms (whiteness size and color) in vitiligo patients

Public title

Effect of safflower honey-based topical product in treatment of vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having clear vitiligo lesions with the dermatologist approval Involvement of less than 10% of the body surface

Exclusion criteria:

pregnancy or breastfeeding local treatment of vitiligo in the last 4 weeks or systemic treatment or phototherapy in the last 12 weeks progress in the last 6 weeks serious underlying disease or use of immunosuppressive drugs

Age

From **12 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Randomization is simple and each participant is randomly assigned the main intervention treatment or the control group treatment. Randomization unit: individual. Randomization tool: statistical software and sealed envelope. A code is assigned to each sealed envelope by the software, and one of these codes is randomly assigned to each participant by the software, and the corresponding envelope containing the medicine is delivered to the patient. The person who registers the codes in the software is different from the person who delivers the envelopes.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient who entered the study with informed consent does not know the type of treatment. The person who saves the assigned codes and inserts them on the envelopes has no connection with the patients. The researcher and the clinical caregiver are not aware of the contents of the envelopes. The outcome evaluator will be informed only if a serious side effect, after which the patient is excluded from the study. The data analyst and

the data safety and monitoring committee will not be informed about the identity of the participants.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahid University

Street address

Persian Gulf Freeway

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2023-01-02, 1401/10/12

Ethics committee reference number

IR.SHAHED.REC.1401.120

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

vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

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

The extent of vitiligo lesions

Timepoint

Measuring the extent of vitiligo lesions at the beginning of the study (before the start of the intervention) and 28 and 84 days after the start of using the honey-based safflower topical product.

Method of measurement

Calculating the area of the lesion using transparent graded paper

2**Description**

Color index of vitiligo lesions

Timepoint

Measurement of the color index of vitiligo lesions at the beginning of the study (before the start of the intervention) and 28 and 84 days after the start of the use of honey-based safflower topical product.

Method of measurement

Comparison of whitening rate with healthy skin, (completely white 100%; slightly colored white 90%; whiteness more than colored 75%; Whiteness and colored equal to 50%; Whiteness less than colored 75%; brief whiteness 10%; Natural skin color%0) by observation and photography.

3

Description

Vitiligo Area Scoring Index (VASI)

Timepoint

Measurement of the Vitiligo Area Scoring Index (VASI) at the beginning of the study (before the start of the intervention) and 28 and 84 days after the start of using the honey-based safflower topical product.

Method of measurement

We multiply the color index of each lesion by the percentage of involvement of each lesion compared to the whole skin of the body and add up the obtained numbers.

4

Description

Quality of life score in VitiQoL questionnaire

Timepoint

Fill out vitiligo quality of life questionnaire at the beginning of the study (before the start of the intervention) and 84 days after starting the use of honey-based safflower topical product.

Method of measurement

Vitiligo quality of life questionnaire (VitiQoL)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Applying a thin layer of honey-based safflower topical product to the affected area twice a day

Category

Treatment - Drugs

2

Description

Control group: Applying a thin layer of 0.1% tacrolimus ointment to the lesion site twice a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان پوست رازی

Full name of responsible person

نرگس قندی

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vahdat-e-Eslami Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

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

Shahed University

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

Shahed University

Full name of responsible person

Mohammadreza Najjarzadeh

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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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 is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic, scientific and research institutions

Under which criteria data/document could be used

It is allowed to use the data for the purpose of meta-analyses and by preserving all the rights of the creators of this data.

From where data/document is obtainable

By referring to the scientific officer of the research Ms. Dr. Fatemeh Emadi at the email address fatemeh12emadi@yahoo.com and at the address of Shahid University, Fars Gulf Highway, Tehran, Tehran Province, Iran. zip code 3319118651. contact number 00982151214055.

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

The applicant's request will be sent to the mentioned e-mail containing the applicant's profile, the purpose of receiving the data, and the details of the desired data, and it will be checked for compliance of the conditions and data requested with the publication conditions within a maximum of one month, and an appropriate response

will be sent.

Comments