

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the therapeutic effects of four topical drugs on patients with vitiligo referred to the dermatological clinics of Isfahan University of Medical Sciences

Protocol summary

Study aim

Comparison of safety and efficacy of 4 topical drugs of clobetasol, clobetasol + propylene glycol + aspirin + copper sulfate + methoxsalen 0.01%, clobetasol + propylene glycol + aspirin + copper sulfate + methoxsalen 0.005%, and clobetasol + propylene glycol + aspirin + copper sulfate in the treatment of vitiligo

Design

Phase III four-arm triple-blind randomized trial with parallel groups on 60 patients, randomization will be performed by sealed envelopes.

Settings and conduct

This study will include 60 patients with vitiligo referred to the dermatology clinic of Sedighe Tahere Hospital, Isfahan. The patients will be randomized into 4 groups. The participants, the investigator, the assessor, and even the data analyzer will be unaware of the drug received by the patients. Application of cream will be daily and left for at least 3 hours on the skin while avoiding direct sun exposure. Perifollicular pigmentation will be evaluated at the beginning and 3 months since the initiation of treatments and patient satisfaction only 3 months after.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 16-60 years Lesions of the extremities, trunk, and face Exclusion criteria: Follicular pigmentation White hair in the lesion Lesions at the distal end of the extremities Genital, periungual, or skin fold lesions Topical treatment or phototherapy within the past month Pregnancy

Intervention groups

First group: clobetasol 0.5% Second group: clobetasol 0.5% + propylene glycol 5% + aspirin 1% + copper sulfate 0.1% + methoxsalen 0.01% Third group: clobetasol 0.5% + propylene glycol 5% + aspirin 1% + copper sulfate 0.1% + methoxsalen 0.005% Fourth group: clobetasol 0.5% + propylene glycol 5% + aspirin

1% + copper sulfate 0.1%

Main outcome variables

Perifollicular pigmentation improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220117053743N2**

Registration date: **2022-05-09, 1401/02/19**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-18, 1401/04/27**

Update count: **1**

Registration date

2022-05-09, 1401/02/19

Registrant information

Name

Aida Farmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3261 6408

Email address

aida.farmani.med@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-06, 1400/12/15

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effects of four topical drugs on patients with vitiligo referred to the dermatological clinics of Isfahan University of Medical Sciences

Public title

Comparison of the therapeutic effects of four topical drugs in the treatment of vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 16-60 years Involvement of <20% total body surface area Lesions on the extremities, trunk, and face

Exclusion criteria:

Follicular pigmentation White hair in the lesion Lesions at the distal end of the extremities Genital, periungual, and skin fold lesions Topical treatment or phototherapy within the past month Pregnancy

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with individuals as units of randomization along with allocation concealment: 60 unclear envelopes and 60 cards with the names of the groups (A, B, C, D) will be prepared (15 cards for each group). The cards will be put into the envelopes and the envelopes will be sealed and provided to the investigator. Upon entrance of each patient to the study, the envelopes will be shuffled and one will randomly be selected. The patient will be allocated to group A, B, C, or D based on the card inside the selected envelope.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The topical drugs will be prepared by the personnel of a pharmaceutical company uninvolved in the study in four tubes of similar shape and color labeled A, B, C, and D. One tube will be delivered to each patient by the investigator based on their group. Thus, the participants,

the investigator, the assessor, and even the data analyzer will be unaware of the drug received by the patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjarib street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-04-11, 1401/01/22

Ethics committee reference number

IR.MUI.MED.REC.1401.013

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

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

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

Perifollicular pigmentation improvement

Timepoint

Three months after the initiation of treatments

Method of measurement

1) mild: 0-25%, 2) moderate: 26-50%, 3) good: 50-75%, 4) excellent: >75%

Secondary outcomes

1

Description

Patient satisfaction with treatments

Timepoint

Three months after the initiation of treatments

Method of measurement

Visual Analogue Scale

2

Description

Side effects

Timepoint

During treatments

Method of measurement

Patient reports of observation by the specialist

Intervention groups

1

Description

Intervention group: clobetasol 0.05% (Raha Pharmaceutical Co., Iran) daily on the lesions remaining for at least 3 hours while avoiding direct sun exposure

Category

Treatment - Drugs

2

Description

Intervention group: clobetasol 0.05% + propylene glycol 5% + aspirin 1% + copper sulfate 0.1% + methoxsalen 0.01% (all medication from Raha Pharmaceutical Co., Iran) daily on the lesions remaining for at least 3 hours while avoiding direct sun exposure

Category

Treatment - Drugs

3

Description

Intervention group: clobetasol 0.05% + propylene glycol 5% + aspirin 1% + copper sulfate 0.1% + methoxsalen 0.005% (all medication from Raha Pharmaceutical Co., Iran) daily on the lesions remaining for at least 3 hours while avoiding direct sun exposure

Category

Treatment - Drugs

4

Description

Intervention group: clobetasol 0.05% + propylene glycol 5% + aspirin 1% + copper sulfate 0.1% (all medication from Raha Pharmaceutical Co., Iran) daily on the lesions remaining for at least 3 hours while avoiding direct sun exposure

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sedighe Tahereh Hospital

Full name of responsible person

Aida Farmani

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Feyz St., Khoram St., Isfahan, Sedighe Tahereh Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash

Street address

Isfahan University of Medical Sciences, Isfahan, Iran

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Aida Farmani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Dermatology department, Alzahra Hospital, Isfahan, Iran

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Person responsible for updating data

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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City

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Province

Isfahan

Postal code

8174673461

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available