Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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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 phototherpay 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
Isfehan
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
Street address
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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aida.farmani.med@gmail.com
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 scientific inquiries

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Person responsible for updating data

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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