# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 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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**Province**
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**Postal code**
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**Email**
aida.farmani.med@gmail.com

## 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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**Province**
Isfehan
**Postal code**
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+98 31 3668 0048
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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 scientific inquiries

**Contact**

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Aida Farmani

**Position**
Resident

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Dermatology

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## Person responsible for updating data

**Contact**

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**Position**
Resident

**Latest degree**
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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