

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Investigating the effect of adding oral fluoxetine to topical corticosteroid treatment in patients with limited vitiligo form

Protocol summary

Study aim

Comparison of the therapeutic effects of oral fluoxetine and topical clobetasol with topical clobetasol alone in vitiligo patients referred to the Dermatology Clinic of Isfahan University of Medical Sciences.

Design

Patients referred to the clinic, clinical trial with a control group, two groups of 50 patients

Settings and conduct

Vitiligo patients referred to the teaching clinic of Isfahan University of Medical Sciences

Participants/Inclusion and exclusion criteria

1. Age more than 16 years and under 60 years □. Lack of follicular pigmentation 3. Absence of white hair in the lesion 4. Their lesions should be on the organs and trunk, except for the areas of the ends of the organs, genitalia, periungual and folds 5. Have not received any topical treatment or phototherapy during the last 1 month 6. The extent of involvement is less than 20% of the total body surface. □. No history of any psychiatric disorder 8. No simultaneous use with monoamine oxidase inhibitor drugs (MAOI) 9. No history of hypersensitivity reaction to fluoxetine or any of the ingredients in the formulation 10. Patients who have not complied with the conditions of taking the drug, such as the prescription for taking the drug, continuing to take the drug, and not taking any other skin drug that affects vitiligo; 11. Female patients who became pregnant during the study.

Intervention groups

The first group is treated with 20 mg fluoxetine tablets and 0.05% clobetasol cream, and the second group is treated only with 0.05% clobetasol cream.

Main outcome variables

The size of the lesion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221020056251N1**

Registration date: **2023-02-28, 1401/12/09**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-28, 1401/12/09**

Update count: **0**

Registration date

2023-02-28, 1401/12/09

Registrant information

Name

mohammad reza pordeli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3253 7349

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of adding oral fluoxetine to topical corticosteroid treatment in patients with limited vitiligo form

Public title

Effect of fluoxetine treatment of vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Have not received any topical treatment or phototherapy during the past month. Lack of follicle pigmentation
Absence of white hair in loss Their lesions should be on the limbs and trunk, except for the ends of the limbs and genitalia and around the nails and folds The extent of involvement is less than 20% of the total body surface.
No history of any psychiatric disorder No simultaneous use with monoamine oxidase inhibitor drugs (MAOI) No history of hypersensitivity reaction to Fluoxetine or any of the compounds in the formulation

Exclusion criteria:**Age**

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**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

hezarjerib blvd

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-06-29, 1401/04/08

Ethics committee reference number

IR.MUI.MED.REC.1401.141

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

vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

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

The size of the lesion

Timepoint

3 months after starting treatment

Method of measurement

The surface area of the lesion

Secondary outcomes

empty

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

Intervention group: Clobetazol ointment is used daily for 3 hours and Fluoxetine 20 tablets are used daily for 3 months. The training class on how to take the drugs is given once for each patient.

Category

Treatment - Drugs

2**Description**

Control group: Clobetazol ointment is used for 3 hours daily for 3 months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sedige Tahereh Hospital

Full name of responsible person

dr nazila pootiyan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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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