

# 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

m.pordeli77@gmail.com

#### 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

**Street address**

Sedige Tahereh Hospital, Faiz St, Khorram St ,Isfahan,

**City**

Isfahan

**Province**

Isfahan  
**Postal code**  
8174673461  
**Phone**  
+98 31 3335 9090  
**Email**  
m.pordeli77@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 Research  
Assistant,Isfahan University of Medical  
Sciences,Isfahan,Iran  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174673461  
**Phone**  
+98 31 3668 0048  
**Email**  
m.pordeli77@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**  
Dr nazila poostiyan  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**

Dermatology  
**Street address**  
Department of Dermatology,Al-Zahra  
Hospital,Isfahan,Iran  
**City**  
isfahan  
**Province**  
Isfahan  
**Postal code**  
8174673461  
**Phone**  
+98 31 3668 0048  
**Email**  
n.poostiyan@med.mui.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Dr nazila poostiyan  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
Department of Dermatology,Al-Zahra  
Hospital,Isfahan,Iran  
**City**  
isfahan  
**Province**  
Isfahan  
**Postal code**  
8174673461  
**Phone**  
+98 31 3261 6408  
**Email**  
m.pordeli77@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
mohammad reza pordeli  
**Position**  
student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
General Practitioner  
**Street address**  
Department of Dermatology,Al-Zahra  
Hospital,Isfahan,Iran  
**City**  
isfahan  
**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3261 6408

**Email**

m.pordeli77@gmail.com

**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