

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Comparison of efficacy of topical clobetasol 0.05% plus 5FU 5% cream vs. topical clobetasol 0.05% alone in the treatment of vitiligo.

#### Protocol summary

##### Summary

Many medical treatments have been attempted with partial success for vitiligo, but there is no previous trial on combination of topical 5FU 5% and clobetasol. . This double-blind clinical trial from November 2009 to August 2011 on patients admitted to the educational clinics vitiliginous skin was performed. 45 patients were enrolled. Each patient with two patches was selected that for one side clobetasol cream and other side clobetasol and 5fu for 3 months, every other day was administered.pigmentation score was evaluated at the end of treatment. Inclusion criteria were as follow: vitiligo patients with at least 2 lesions on the body, >15 years old, lack of follicular pigmentation (score=0), lack of white hair over the lesion and disease stability within the last 6 months. Exclusion criteria were as follow: those who had recieved topical medication for at least 1 month and systemic medication or phototherapy for at least 3 months prior to inclusion; past medical history of liver, kidney and hematologic disorders; the vitiligo lesions on the face, genitalia or acral areas; pregnancy or lactation and the segmental subtype.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201203049198N2**

Registration date: **2012-04-01, 1391/01/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-04-01, 1391/01/13

##### Registrant information

###### Name

Fatemeh Mokhtari

##### Name of organization / entity

Isfahan Univercity of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1444 6330

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2009-10-23, 1388/08/01

##### Expected recruitment end date

2011-08-23, 1390/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of efficacy of topical clobetasol 0.05% plus 5FU 5% cream vs. topical clobetasol 0.05% alone in the treatment of vitiligo.

##### Public title

Comparison of efficacy of topical clobetasol 0.05% plus 5FU 5% cream vs. topical clobetasol 0.05% alone in the treatment of vitiligo.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria were as follow: vitiligo patients with at least 2 lesions on the body, >15 years old, lack of follicular pigmentation (score=0), lack of white hair over the lesion and disease stability within the last 6 months.

Exclusion criteria were as follow: those who had recieved topical medication for at least 1 month and systemic medication or phototherapy for at least 3 months prior to inclusion; past medical history of liver, kidney and hematologic disorders; the vitiligo lesions on the face, genitalia or acral areas; pregnancy or lactation and the segmental subtype. Patients were instructed about the study protocol, possible side effects and a written informed consent was taken from all patients before enrollment.

**Age**

From **17 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **45**

**Randomization (investigator's opinion)**

N/A

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

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

not used

**Secondary Ids**

empty

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

Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Soffeh Blvd,  
Isfahan

**City**

Isfahan

**Postal code****Approval date**

2009-10-23, 1388/08/01

**Ethics committee reference number**

388456

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

Vitiligo

**ICD-10 code**

L80

**ICD-10 code description**

vitiligo

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

Lesion of vitiligo

**Timepoint**

End of three months

**Method of measurement**

Pigmentation score

**Secondary outcomes****1****Description**

erythema,atrophy,erosion

**Timepoint**

any time during treatmrnt

**Method of measurement**

observation

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

In control group: Clobetasol 0.05% cream for topical use over the selected lesion on the left side of the body was given to patient . we recommended that patient use the drug every other day,once a day. The duration of study was three months.

**Category**

Treatment - Drugs

**2****Description**

In interventionl group: Clobetasol 0.05% cream plus 5FU5% cream for topical use over the selected lesion on the right side of the body was given to patient . we recommended that patient use the drug every other day,once a day. The duration of study was three months.

**Category**

Treatment - Drugs

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

skin educational clinics

**Full name of responsible person**

dr.zabihollah shahmoradi

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Alzahra hospital, Soffeh Blvd, Isfahan

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Isfahan

shahmoradi@mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr.Peyman Adibi

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Isfahan University of Medical Sciences, Soffeh Blvd,  
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Isfahan

**Grant name**

388456

**Grant code / Reference number**

388456

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Isfahan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

dr.zabihollah shahmoradi

**Position**

Assistant professor of Dermatology

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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resident of skin

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*  
**Analytic Code**  
*empty*

**Data Dictionary**  
*empty*