

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

f_mokhtari@resident.mui.ac.ir

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

Street address

Alzahra hospital, Soffeh Blvd, Isfahan

City

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

Street address

Isfahan University of Medical Sciences, Soffeh Blvd,
Isfahan

City

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

Street address

Isfahan University of Medical Sciences, Soffeh Blvd,
Isfahan

City

Isfahan

Postal code

Phone

+98 31 1666 6666

Fax

+98 66 66666

Email

shahmoradi@mui.ac.ir

Web page address

Person responsible for scientific 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

Street address

Isfahan University of Medical Sciences, Soffeh Blvd,
Isfahan

City

Isfahan

Postal code

Phone

+98 31 1666 6666

Fax

+98 31 1666 6666

Email

shahmoradi@mui.ac.ir

Web page address

shahmoradi@mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

dr.fatemeh mokhtari

Position

resident of skin

Other areas of specialty/work

Street address

Isfahan University of Medical Sciences, Soffeh Blvd,
Isfahan

City

Isfahan

Postal code

Phone

+98 31 1666 6666

Fax

Email

f_mokhtari@resident.mui.ac.ir

Web page address

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