

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparing the outcomes of 1% pimecrolimus cream with 0.1% mometasone cream in treatment of childhood vitiligo in the face, neck and trunk

Protocol summary

Study aim

Comparing the outcomes of 1% pimecrolimus cream with 0.1% mometasone cream in treatment of childhood vitiligo in the face, neck and trunk

Design

Randomised, superiority, parallel group trial with not blinded outcome assessment. Randomisation was centralised and computerised with random number generation. study population will be 64 cases in 2 groups.

Settings and conduct

the patients referred to alzahra and sedighe tahere dermatology clinics of Isfahan who are under 18 will be included in the study and will get visited at the start of the study, and 2 and 3 months after the initiation of the treatment. the patients own satisfaction of the treatment and the decrease in the lesions size will be assessed and all the lesions will get photographed and the improvement in pigmentation will be assessed and scored by two expert dermatologists

Participants/Inclusion and exclusion criteria

entrance conditions include vitiligo lesion in less than 10 percent of body surface , non segmental vitiligo, no history of allergic reaction to used drugs excluding criteria includes pregnancy, lactating, using other treatments for vitiligo in the last 6 months, allergic reaction to used drugs

Intervention groups

first group goes under treatment using pimecrolimus 1% topically twice a day and the second group of intervention goes under treatment with mometasone 0.1% topically daily.

Main outcome variables

Visual Analogue Scale score of improvement according to the patients; mean decrease in lesions size; pigmentation improvement in the lesions according to 2 experts

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230307057646N1**

Registration date: **2023-05-19, 1402/02/29**

Registration timing: **prospective**

Last update: **2023-05-19, 1402/02/29**

Update count: **0**

Registration date

2023-05-19, 1402/02/29

Registrant information

Name

Sarah Seyedyousefi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3630 5800

Email address

sarah.syousefi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2024-04-03, 1403/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the outcomes of 1% pimecrolimus cream with 0.1% mometasone cream in treatment of childhood vitiligo in the face, neck and trunk

Public title

Comparing the outcomes pimecrolimus and mometasone cream in treatment of childhood vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Vitiligo in less than 10 percent of body surface non-segmental vitiligo no history of allergic reaction to used drugs

Exclusion criteria:

pregnancy and lactating using other treatments for vitiligo lesions in last 6 months severe allergic reactions to used drugs

Age

To **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

31 random numbers were generated using the random number generator function of the website calculator.net. the participants are numbered according to the order of addition to the study and the participants with the numbers mentioned before, will be assigned to the group with pimecrolimus as a treatment and others will be assigned to the mometasone group.

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

Ethics Committee of Isfahan university of medical

sciences , Isfahan university of medical sciences, hezar jarib avenue, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2023-03-06, 1401/12/15

Ethics committee reference number

IR.ARI.MUI.REC.1401.322

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Visual Analogue Scale score of improvement according to the patients

Timepoint

3 months after the initiation of the treatments

Method of measurement

patients score the improvement from 1-10

2

Description

mean changes in lesions size

Timepoint

2 and 3 months after the initiation of the treatment

Method of measurement

millimeter sensitive ruler

3

Description

pigmentation improvement in the lesions according to 2 experts

Timepoint

2 and 3 months after the initiation of the treatment

Method of measurement

2 experts in dermatology scoring the improvement from 0 to 3

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: pimecrolimus 1% cream, topical use , twice a day for 2 months

Category

Treatment - Drugs

2

Description

Intervention group: Mometasone 0.1% cream, topical use , daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr. Fariba Iraji

Street address

Sofeh Blvd , Alzahra Hospital

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2

Recruitment center

Name of recruitment center

Sedigheh Tahereh dermatology clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr gholamreza Asgari

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research and technology vice chancellor of Isfahan university of medical sciences, Isfahan university of medical sciences, Hezar jarib avenue, Isfahan , Iran

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research@mui.ac.ir

Web page address

<https://researchold.mui.ac.ir/>

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

Sarah Seyedyousefi

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

Dermatology

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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

the possible decline of cooperation by parents considering the cultural background

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

patients data will not be available and only the final result (the changes in lesion size and pigmentation and patients' satisfaction) will be published. study method and analysis will be publicly available for interested fellow researchers.

When the data will become available and for how long

6 months after publication

To whom data/document is available

active people in research fields

Under which criteria data/document could be used

active people in research fields who don't have access to the databases can send a request to get access to the data. researchers who are willing to do complementary research projects on the matter can have access to the analysis and the study method. researcher willing to do metanalysis on the matter can request for the data.

From where data/document is obtainable

corresponding author can be accessed via these ways:
Sarah Seyedyousefi E-mail: Sarah.syousefi@gmail.com
postal Address: no.25 , anahita alley , akbaralsadat alley, 15th khordad street, Isfahan phone number:
+989226738926

What processes are involved for a request to access data/document

researchers can request for the data by emailing the corresponding author and providing reasonable explanation

Comments