

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

comparing the additive effect of topical pentoxifylline and phototherapy versus topical tacrolimus and phototherapy in patients with vitiligo

Protocol summary

Study aim

comparing the additive effect of topical pentoxifylline and phototherapy versus topical tacrolimus and phototherapy in patients with vitiligo

Design

Patients who were included in the study were treated with NB-UVB phototherapy and 70 lesions in equal and equal groups were considered symmetrically and randomly in different anatomical regions. The lesions are then randomly treated with pentoxifylline and tacrolimus. Creams are applied twice a day. The contents of both drugs are identical and encoded. The code list is available to the manufacturer of the drug and only two drug groups are divided into the formulator. VASI criteria and quantitative measurements of melanin and erythema of lesion with Dermacatch were used to evaluate patients. In this study, the patients were evaluated three times by the researcher: 1- before the intervention 2- one month after the intervention 3- 3 months after the intervention.

Settings and conduct

Dermatology Clinic of the Shahid Faghihi Hospital, 70 vitiligo lesions were treated in two groups of both intervention and control with two tacrolimus and pentoxifylline triple blinks.

Participants/Inclusion and exclusion criteria

Patients with vitiligo over 14 years of age who have two vitiligo lesions are symmetrical and treated with NB-UVB. Patients have not received systemic or topical medication for the treatment of vitiligo during the past three months. Sensitivity to the two drugs used, pregnant and lactating women, patients with uncontrolled systemic disorders have been excluded.

Intervention groups

In the intervention group, the vitiligo lesion was 10% Pentoxifylline cream and 0.1% Tacrolimus cream was in control group.

Main outcome variables

Qualitative measure with VASI score and quantitative

measurement with dermcatch tool

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120909010795N3**

Registration date: **2019-05-09, 1398/02/19**

Registration timing: **retrospective**

Last update: **2019-05-09, 1398/02/19**

Update count: **0**

Registration date

2019-05-09, 1398/02/19

Registrant information

Name

Nasrin Saki

Name of organization / entity

Dermatology Department, Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 19049

Email address

sakina@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2017-08-23, 1396/06/01

Actual recruitment end date

2018-02-20, 1396/12/01
Trial completion date
 2018-03-16, 1396/12/25

Scientific title
 comparing the additive effect of topical pentoxifylline and phototherapy versus topical tacrolimus and phototherapy in patients with vitiligo

Public title
 Comparison of pentoxifylline and tacrolimus in the treatment of vitiligo patients

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with vitiligo (with clinical diagnosis and Wood's Lamp) Patients with at least two relatively and bilateral lesion. Patients undergoing treatment with NB-UVB Residence in Shiraz, in case of non-residence in Shiraz, may attend meetings required for a visit. Having the ability to understand Persian language written consent to participate in the study.
Exclusion criteria:
 Over the last three months, they have received topical vitiligo medication Unwillingness to receive local interventions

Age
 From **14 years** old to **70 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **35**
 More than 1 sample in each individual
 Number of samples in each individual: **2**
 Two similar lesions and symmetric lesions on both sides of the body in each patient
 Actual sample size reached: **35**
 More than 1 sample in each individual
 Actual sample size in each individual: **2**
 Two similar lesions and symmetric lesions on both sides of the body in each patient

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomization tool, random number table

Blinding (investigator's opinion)
 Triple blinded

Blinding description
 Patients were enrolled with informed consent. The two drugs used in patients were in the same boxes. The drugs were marked with a code and they had the same shape. The prescriber was not aware of the drug

encoding. For each patient, two lesions have been selected at two points in his body. patients did not know the coding of drugs. The treating physician who visited them in three steps did not know the encoding of drugs. The analyzer did not know the coding of the drugs. The author of the draft article did not know the encoding of drugs. The drug code was only available to the manufacturer of the drug, which has been available to other researchers after writing the draft article.

Placebo
 Not used
Assignment
 Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Shiraz University of Medical Sciences
Street address
 shahid faghihi hospital, zand Blvd
City
 shiraz
Province
 Fars
Postal code
 71348846114
Approval date
 2017-08-23, 1396/06/01
Ethics committee reference number
 IR.SUMS.MED.REC.1397.296

Health conditions studied

1

Description of health condition studied
 vitiligo
ICD-10 code
 L80
ICD-10 code description
 Vitiligo

Primary outcomes

1

Description
 pigmentation
Timepoint
 At the beginning of the study, one month and three months after starting treatment
Method of measurement
 Qualitative measure with VASI score and quantitative

measurement with dermocatch tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 35 vitiligo lesions have been treated locally with pentoxifylline in patients with NBUVB treated light therapy. Pentoxifylline was 10% in the form of a topical cream. This drug was made by the Faculty of Pharmacy of Shiraz University of Medical Sciences. The method of making drug was incorporation on the basis of cold cream .

Category

Treatment - Drugs

2

Description

Control group: 35 Vitiligo lesions have been treated topically with tacrolimus in patients with NBUVB treated light therapy. Tacrolimus is a topical cream of 0.1%. This drug is made by aburaihan pharmaceutical Co, a brand name of moduproc.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi Hospital

Full name of responsible person

nasrin saki

Street address

dermatology ward, shahid faghihi hospital, zand Blvd

City

shiraz

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7134846114

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+98 71 3231 9049

Email

sakina@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Yoones Ghasemi

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd.

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Nasrin Saki

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Information on the outcome of the disease is sharing.

When the data will become available and for how long

3 months after the publication of results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

To conduct similar clinical trials

From where data/document is obtainable

Electronic correspondence with research officer

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

By emailing the correspondent researcher or telephone, within a period of one month, research documentation will be available.

Comments