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 inpateints with vitiligo

Protocol summary

Study aim
comparing the additive effect of topical pentoxifylline and phototherapy versus topical tacrolimus and phototherapy inpateints with vitiligo

Design
Patients who were included in the study were treated with NBUVB phototherapy and 70 lesions in equal and equal groups were considered symmetrically and randomistically 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 Dermukach 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 blinds.

Participants/Inclusion and exclusion criteria
Patients with vitiligo over 14 years of age who have two vitiligo lesions are symmetrical and treated with NBUVB. Patients have not received systemic or topical medication for the treatment of Vigiloga 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 dermocatch 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)

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+98 23 19049

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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 inpateints 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 NBUVB 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Yoones Ghasemi
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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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Position
Assistant Professor

Latest degree
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Person responsible for updating data

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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 corresponder researcher or telephone, within a period of one month, research documentation will be available.

Comments