

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison between fluocinolone plus tacrolimus and fluocinolone plus NBUVB in the treatment of localized morphea

Protocol summary

Study aim

Comparison between fluocinolone plus tacrolimus and fluocinolone plus NBUVB in the treatment of localized morphea

Design

This is a Phase 3 clinical trial study of randomized controlled and no blinding with parallel groups. Patients with active localized morphea with a maximum size of 10 cm² in 20 individuals who were randomly assigned to two groups of 10 using Rand List software 1: Fluocinolone treatment with topical tacrolimus 2: Fluocinolone treatment with NBUVB Will take.

Settings and conduct

In this study, 20 patients with active localized morphea who referred to Sina Hospital's dermatology clinic were randomly assigned to two groups of 10 interventions (fluocinolone ointment with topical tacrolimus) and control (fluocinolone ointment with NBUVB).

Participants/Inclusion and exclusion criteria

Inclusion criteria: • The disease is in its active phase • Patients have not received any treatment in the past 6 weeks • Existence of at least one morphea plaque with a total area of 10 cm² • Do not use immunosuppressants or phototherapy in the last three months Non-entry criteria: Systemic sclerosis or pseudosclerosis - Existence of a history of side effects in previous use of tacrolimus (hypersensitivity, intolerance) - Having radiotherapy contraindications Pregnant women or those who are planning to become pregnant during treatment - Breastfeeding women

Intervention groups

Intervention group: receiving topical fluocinolone ointment with topical tacrolimus. In the intervention group of 10 patients with localized morphea, topical fluocinolone ointment with topical tacrolimus will be given every 12 hours for 4 months. In the control group of 10 patients with localized morphea, fluocinolone ointment will be given every 12 hours and NBUVB 3 times a week for 4 months.

Main outcome variables

Waste area; Dispigmentation; Stiffness; Atrophic extent of lesions and patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091012002581N7**

Registration date: **2020-09-05, 1399/06/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-05, 1399/06/15**

Update count: **0**

Registration date

2020-09-05, 1399/06/15

Registrant information

Name

Hamide Herizchi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 4650

Email address

herizchih@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between fluocinolone plus tacrolimus and fluocinolone plus NBUVB in the treatment of localized morphea

Public title

Comparison between fluocinolone plus tacrolimus and fluocinolone plus NBUVB in the treatment of localized morphea

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The disease is in its active phase Patients have not received any treatment in the past 6 weeks Existence of at least one morphea plaque with a total area of cm² 10 Lack of use of immunosuppressants, penicillamine, interferon gamma, or phototherapy in the last three months

Exclusion criteria:

Systemic sclerosis or pseudosclerosis Existence of a history of side effects in previous use of tacrolimus (hypersensitivity, intolerance) Contraceptive radiation therapy Pregnant women or those who are planning to become pregnant during treatment Breastfeeding women Infectious active lesion at the site of morphea plaque Recent vaccinations (28 days before the start of the study) Borrelia burgdorferi infection (serological diagnosis)

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked*No information***Sample size**

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization will be carried out on an individual basis by Rand List software. The allocation will be sealed by an independent monitor and will not be broken until the end of the study.

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 Tabriz University of Medical Sciences

Street address

Daneshgah

City

Tabriz

Province

East Azarbaijan

Postal code

5142954481

Approval date

2020-07-20, 1399/04/30

Ethics committee reference number

IR.TBZMED.REC.1399.401

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

Localized morphea

ICD-10 code

L94.0

ICD-10 code description

Localized scleroderma [morphea]

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

Morphea waste area

Timepoint

Months 0 -2- 4

Method of measurement

Measurement with ruler

2**Description**

Dispigmentation

Timepoint

Months 0 -2- 4

Method of measurement

16 megapixel digital camera from a distance of 10 cm from the lesion

3**Description**

Hardness

Timepoint

Months 0 -2- 4
Method of measurement
Observe and pinch through the lesion

4

Description

Atrophy

Timepoint

Months 0 -2- 4

Method of measurement

View and touch as well as digital camera

Secondary outcomes

1

Description

Patient satisfaction after treatment

Timepoint

Months 0- 2- 4

Method of measurement

Patient serial examination - questionnaire

Intervention groups

1

Description

Intervention group: 10 people with localized morphea will be treated with topical ointment fluocinolone and tacrolimus 0.1 percent every 12 hours for 4 months.

Category

Treatment - Other

2

Description

Control group: 10 people with localized morphea treated with topical fluocinolone ointment every 12 hours with phototherapy with NBUVB will be given three sessions a week for 4 months.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Hamideh Herizchi

Street address

Azadi Street

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Tabriz

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East Azarbaijan

Postal code

5163639888

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Email

Drherizchi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ataa Mahmoudpour

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Hamide Herizchi Ghadim

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

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Tabriz University of Medical Sciences
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Dr Hamide Herizchi Ghadim
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Associate professor
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Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Forough Yadegari
Position
Resident
Latest degree
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Other areas of specialty/work
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be shared after being unidentified.

When the data will become available and for how long

All any time

To whom data/document is available

It will be free for every one.

Under which criteria data/document could be used

There are no special conditions.

From where data/document is obtainable

Email: Drherizchi@yahoo.com, 09141168780, Dr Hamide Herizchi Ghadim, Dermatology Department - Sina Hospital - Azadi sreet - Tabriz.

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

The request will be checked, then data will be sent by Email in 1 month.

Comments