Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparing the efficacy of 50% dimethyl sulfoxide solution versus topical tretinoin 0.5% cream in patients with cutaneous amyloidosis

Protocol summary

Study aim

The present study was designed to compare the efficacy of 50% dimethyl sulfoxide topical solution versus tretinoin 0.5% cream in treating primary localized cutaneous amyloidosis.

Design

Split-side, own control, double-blinded controlled clinical trial

Settings and conduct

Ten patients (three iterations on type I error of 5%, Zα/2 = 1.96, Zβ = 0.84) with primary cutaneous amyloidosis refer to dermatology clinics, Faghihi hospital, Shiraz, will enroll. Although the treatments will be allocated randomly, the patients are aware of the treatments. The blinded principal dermatologist measures baseline melanin, erythema, and itching quantitative values at baseline for each side separately. Patients receive dimethyl sulfoxide 50% topical solution and tretinoin 0.5% cream on the assigned side for twenty weeks. They instruct by a blinded dermatologist to apply treatments daily in the first four weeks and every other day later on. Patients reattend the Faghihi hospital dermatology clinic and further colorimetery, itching scoring, and photography undertake at the end of 4th, 12th, and 18th week follow ups with the dermatologist unaware of the treatments' side.

Participants/Inclusion and exclusion criteria

Patients will include if they have bilateral macular or lichen amyloidosis, confirmed by H&E staining, and were over 18 years of age. Volunteers will exclude from the study if they have hypersensitivity to retinoids, are taking topical agents in recent four weeks, are pregnant or lactating, are hepatic disorders, or have not consent to photography.

Intervention groups

Patients receive dimethyl sulfoxide 50% topical solution (intervention, formulized and prepared at the School of Pharmacy, Shiraz) and tretinoin 0.5% cream (control, Iran Daroo, Tehran, Iran) on the assigned side daily for 4 weeks and every other day to the 20th week..

Main outcome variables

melanin; erythema; itching score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181114041658N1**
Registration date: **2019-02-24, 1397/12/05**
Registration timing: **prospective**

Last update: **2019-02-24, 1397/12/05**
Update count: **0**

Registration date

2019-02-24, 1397/12/05

Registrant information

Name

alireza heiran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3233 1634

Email address

stud6730013176@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of 50% dimethyl sulfoxide solution versus topical tretinoin 0.5% cream in patients with cutaneous amyloidosis

Public title

Comparing dimethyl sulfoxide solution versus topical tretinoin in cutaneous amyloidosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with clinical and pathological diagnosis of lichen and macular amyloidosis in trunk and lower limbs bilateral amyloidosis

Exclusion criteria:

using other topical drugs in last four weeks sensitivity to retinoids hepatic disorders breast feeding pregnancy no consent for photography

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **2**

each side of trunk or lower limb serves as one sample

Randomization (investigator's opinion)

Randomized

Randomization description

We use simple randomization by the random number table in order to generate random sequence. To this end, a biostatistician employs the random allocation software and after obtaining the reading trend, the first number will assign to the right side and the second number will assign to the left side. The odd number and even number represent the intervention and control sides, respectively. Therefore, dimethyl sulfoxide and tretinoin will be assigned for each side (right or left). Then, allocation concealment will be done using SNOSE method and numbered, sealed and opaque envelopes by a medical doctorate candidate will be sequenced and will be delivered to the principal dermatologist. In time of enrolling the participants to the study who is fulfilled the inclusion criteria, evaluated by the dermatologist, two consecutive envelops will be open and the allocated sides will be obtained. Each patient will serve as his/her own control; by doing so, the problem of confounding factor will be avoided. Also, for concealment, we will use similar containers in shape and color.

Blinding (investigator's opinion)

Double blinded

Blinding description

Although the treatments were allocated randomly, the patients were aware of the treatments (dimethyl sulfoxide solution and tretinoin cream can be distinguished). They instructed by a blinded dermatologist (Researchers will be blinded to the allocation until the end of study. To conceal group allocation, we use similar containers in shape and color) to apply treatments daily in the first four weeks and every other day later on. Notably, tubes are identical and based on list and number on tubes, will be assigned to each side in every patient. Also, the baseline outcomes will record. Patients reattended and further colorimetery, itching scoring, and photography were then undertaken at the end of 4th, 12th, and 18th week follow ups with the dermatologist unaware of the treatments' side which the volunteer had been randomized. Additionally, dermatologist will record the outcomes as well. Data analysis will be done by an epidemiologist who is unaware of treatments.

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

Local Ethics Committee, Shiraz University of Medical Sciences, Setad Squ., Zand Blvd., Shiraz.

City

Shiraz

Province

Fars

Postal code

7176913861

Approval date

2018-12-17, 1397/09/26

Ethics committee reference number

IR.SUMS.MED.REC.1397.388

Health conditions studied

1

Description of health condition studied

Primary localized cutaneous amyloidosis

ICD-10 code

E85.4

ICD-10 code description

Organ-limited amyloidosis

Primary outcomes

1

Description

melanin

Timepoint

baseline and at the end of 4th, 12th, and 18th week of 20-week treatment period

Method of measurement

colorimetery (dermocatch)

2

Description

itching

Timepoint

baseline and at the end of 4th, 12th, and 18th week of 20-week treatment period

Method of measurement

itching scoring (0-10)

3

Description

erythema

Timepoint

baseline and at the end of 4th, 12th, and 18th week of 20-week treatment period

Method of measurement

colorimetery (dermocatch)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group receives topical dimethyl sulfoxide (DMSO) 50% solution (formulized and prepared at the School of Pharmacy, Shiraz University of Medical Sciences) on the assigned side daily for 4 weeks and every other day to the 20th week. After cleansing the target lesion with water and soap, topical DMSO 50% solusion applies by a spigot.

Category

Treatment - Drugs

2

Description

Control group uses tretinoin 0.5% (Iran Daroo, Tehran, Iran) on the assigned side daily for 4 weeks and every other day to the 20th week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faghihi hospital

Full name of responsible person

Nasrin Saki

Street address

Dermatology clinic, Faghihi hospital, Setad Sque., Zand Blvd., Shiraz.

City

Shiraz

Province

Fars

Postal code

7176913861

Phone

+98 71 3231 9049

Fax

+98 71 3231 9049

Email

nasrinsa85@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Younes Ghasemi

Street address

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

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3235 7282

Email

vcrdep@sums.ac.ir

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

Najmeh Ahramyianpour

Position

Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Setad Sque., Zand Blvd., Shiraz.

City

Shiraz

Province

Fars

Postal code

7176913861

Phone

+98 71 3235 1087

Email

najmeh.pour@gmail.com

Person responsible for scientific 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

Street address

Setad Sque., Zand Blvd., Shiraz.

City

Shiraz

Province

Fars

Postal code

7134846114

Phone

+98 71 3235 1087

Email

nasrinsa85@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Alierza Heiran

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

Others

Street address

Setad Sque., Zand Blvd., Shiraz.

City

Shiraz

Province

Fars

Postal code

7176913861

Phone

+98 71 3235 1087

Email

heiran.alireza@gmail.com

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

There is no further information.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available