

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation of the effect of topical Cyclophosphamide compared to topical mometasone in clinical improvement of skin lesions of Cutaneous T cell lymphoma (mycosis fungoides)

Protocol summary

Study aim

Evaluation of the therapeutic effect of topical cyclophosphamide on cutaneous T cell lymphoma (mycosis fungoides)

Design

Phase 3, pilot, parallel group, split body trial, clinical trial, with consecutive sampling, including 20 patients, single blinded, computerized randomized with permuted blocks

Settings and conduct

The study is conducted in the dermatology clinic of Shiraz University of Medical Sciences. The patients use topical cyclophosphamide on a lesion every night and mometasone ointment on a similar lesion at other site of body. The patients are visited by a blinded investigator before intervention, 4, 8 and 12 weeks after starting intervention and are evaluated for Composite Assessment of Index Lesion Severity (CAILS). Due to the difference of drugs, the patients are aware of the type of drugs in each side. Investigator that deliver the drugs are not involved in the outcome assessment. The outcome assessor is not aware of the type of drugs in each patient. Therefore the research will be single-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 years old and more patients with clinically- and histopathologically-approved cutaneous T-cell lymphoma (mycosis fungoides) in stages 1A, 1B, 2A and active patches and plaques
Exclusion criteria: Allergy to drugs used in the study, chemotherapy with cyclophosphamide, staging of disease 2B and more, pregnancy, lactation

Intervention groups

Intervention group: Patients use cyclophosphamide cream on a lesion every night. Control group: Patients use mometasone ointment on similar lesion on other site of body.

Main outcome variables

Composite Assessment of Index Lesion Severity (CAILS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140212016557N12**

Registration date: **2023-11-27, 1402/09/06**

Registration timing: **prospective**

Last update: **2023-11-27, 1402/09/06**

Update count: **0**

Registration date

2023-11-27, 1402/09/06

Registrant information

Name

Mozhdeh Sepaskhah

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 712125239

Email address

sepaskhah@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-09-24, 1403/07/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Evaluation of the effect of topical Cyclophosphamide compared to topical mometasone in clinical improvement of skin lesions of Cutaneous T cell lymphoma (mycosis fungoides)
Public title	Therapeutic Effect of Cyclophosphamide cream on cutaneous lymphoma (mycosis fungoides)
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	clinically- and histologically-approved cutaneous T cell lymphoma (mycosis fungoides) patients staging of disease 1A,2A,1B patients with active patches and plaques
Exclusion criteria:	Allergy to drugs used in the study chemotherapy with cyclophosphemide staging of disease 2B and more pregnancy lactation
Age	From 18 years old
Gender	Both
Phase	3
Groups that have been masked	- Investigator - Outcome assessor
Sample size	Target sample size: 20 More than 1 sample in each individual Number of samples in each individual: 2 Study designed to a lesion on the right side and one in the left side is treated randomly by one of the drugs using block randomization.
Randomization (investigator's opinion)	Randomized
Randomization description	The patients are recruited by consecutive sampling in the study. Randomization is performed by random allocation software and participants are randomly allocated in the intervention or control group. Randomization of 20 participants in the software is performed by randomization blocks size 4 with random ratio of 1:1. The output of the software is a table that shows each side of participant is allocated in the intervention or control group. Using drugs on the right or left side of body is determined randomly.
Blinding (investigator's opinion)	Single blinded
Blinding description	Due to the difference of drugs, the patients are aware of the type of drugs in each side. Investigator that deliver the drugs are not involved in the outcome assessment. The outcome assessor is not aware of the type of drugs in each patient. Therefore the research will be single-blinded.

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	Shiraz University of Medical Sciences, Zand St., Shiraz. Iran
City	Shiraz
Province	Fars
Postal code	7134845794
Approval date	2023-10-09, 1402/07/17
Ethics committee reference number	IR.SUMS.MED.REC.1402.272
Health conditions studied	
1	
Description of health condition studied	cutaneous T cell lymphoma (mycosis fungoides)
ICD-10 code	C84.0
ICD-10 code description	Mycosis fungoides
Primary outcomes	
1	
Description	Composite Assessment of Index Lesion Severity (CAILS)
Timepoint	Before intervention, 4 and 8 and 12 weeks after starting intervention
Method of measurement	Hypo/Hyperpigmentation, erythema, scale, plaque elevation according to severity from 0 - 8 and size cm2 grading in 18 states
Secondary outcomes	

1

Description

patients satisfaction

Timepoint

4 and 8 and 12 weeks after starting intervention

Method of measurement

Greatly decreased = -3 , moderately decreased = -2 , slightly decreased = -1 , no change = 0 , slightly increased = +1, moderately increased = +2 , greatly increased= +3 , Don't know= photograph was not suitable for proper clinical evaluation

2

Description

physician global assessment (PGA)

Timepoint

Before intervention, 4 and 8 and 12 weeks after starting intervention

Method of measurement

Clear: No signs of MF, but postinflammatory discoloration may be present 1= Almost clear: Only minimal patch/plaque visible, scaling, atrophy, and erythema .2= Mild: Slight patch/plaque visible, scaling, atrophy, and erythema. 3=Moderate: Moderate patch/plaque visible, scaling, atrophy, and erythema.4=Severe: Very marked patch/plaque visible, scaling, atrophy, and erythema

Intervention groups

1

Description

Intervention group: topical use of cyclophosphamide 2% cream on the lesion of one side of the body nightly for 3 month by the patient. According to inaccessibility to prepared topical cyclophosphamide , cyclophosphamide ampule (zydus-India) dilute in cream 2% by chemist.

Category

Treatment - Drugs

2

Description

Control group: topical use of mometasone ointment(mometasone furoate 0.1 % kish-medifarm)on the lesion of one side of the body every night for 3 months by the patient.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic, Shahid Faghihi hospital

Full name of responsible person

Mozhdeh Sepaskhah

Street address

Dermatology clinic, Faghihi hospital, Zand St.

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3212 5239

Email

sepaskhah@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hashem Hashempour

Street address

Research Council, Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3235 7282

Email

vcrdep@sums.ac.ir

Grant name

Research grant of the Research Council of Shiraz University of Medical Sciences

Grant code / Reference number

28279

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

Mozhdeh Sepaskhah

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

Street address

Shiraz University of Medical Sciences, Zand St.,
Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

1433671348

Phone

+98 71 3212 5239

Fax

+98 71 3231 9049

Email

sepaskhah@sums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mozhdeh Sepaskhah

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

Street address

Shiraz University of Medical Sciences, Zand St.,
Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

1433671348

Phone

+98 71 3212 5239

Fax

+98 71 3231 9049

Email

sepaskhah@sums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mozhdeh Sepaskhah

Position

Associate professore

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

Street address

Shiraz University of Medical Sciences, Zand St.,
Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

1433671348

Phone

+98 71 3212 5239

Fax

+98 71 3231 9049

Email

sepaskhah@sums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available