

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of blue light versus topical steroid in treatment of plaque psoriasis lesions: A randomized clinical trial

#### Protocol summary

##### Study aim

To compare the efficacy of blue light and topical steroid in treatment of plaque psoriasis lesions

##### Design

This is a double-blind, second phase clinical trial with a non-randomized design. The study incorporates 20 patients with inclusion criteria who refer to the Clinic of Dermatology in the Mashhad-based Ghaem Hospital and Imam Reza Hospital from April 2018 to April 2019. Cutaneous lesions of the patients will be assigned into two groups of light blue or topical steroids without randomization.

##### Settings and conduct

The study is non-blinded and will be performed in the dermatology clinics of Gham and Imam Reza hospitals in Mashhad.

##### Participants/Inclusion and exclusion criteria

Main inclusion criteria comprise of patients suffering from limited psoriatic plaque with at least two bilateral localized plaques and a maximum size of four centimeters; intent to participate; not receiving topical psoriasis medications from at least a month ago and systemic therapy or phototherapy from two months ago; and location of lesions on extremities or trunk. Major exclusion criteria involve history of consuming photosensitizing medications and arthropathic psoriasis.

##### Intervention groups

In the intervention group, the lesions will be treated by light emitted from Lightcure device for 15 minutes per session 3 times weekly for 4 consecutive weeks. In the control group, lesions will be treated by a moderate topical steroid (fluocinonolone ointment 0.1 percent) every eight hours for 4 consecutive weeks.

##### Main outcome variables

The main outcomes include the Localized Psoriasis Severity Index and therapy complications.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140519017756N42**

Registration date: **2018-04-27, 1397/02/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-27, 1397/02/07**

Update count: **0**

##### Registration date

2018-04-27, 1397/02/07

##### Registrant information

##### Name

Mohammad Bagher Roozgar

##### Name of organization / entity

Birjand University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3239 5680

##### Email address

mbroozgar@bums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-21, 1397/01/01

##### Expected recruitment end date

2019-04-20, 1398/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Efficacy of blue light versus topical steroid in treatment of plaque psoriasis lesions: A randomized clinical trial

**Public title**

Effects of blue light and topical steroid on plaque psoriasis lesions

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age from 18 to 80 years Patients suffering from limited psoriatic plaque with at least two bilateral localized plaques and a maximum size of four centimeters Not receiving topical psoriasis medications from at least a month ago and systemic therapy or phototherapy from two months ago Informed written consent to participate in the study The location of lesions on extremities or trunk

**Exclusion criteria:**

history of photodermatosis history of porphyrias History of consuming photosensitizing medications Arthropathic psoriasis

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **20**

More than 1 sample in each individual

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

Cutaneous lesions in the left side of a patient's body will be taken as the intervention and those of the right side as the control group.

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

Cutaneous lesions of the patients will be randomized into two groups of light blue or topical steroids using randomized blocks (1:1 allocation).

**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 Mashhad University of Medical Sciences

**Street address**

Daneshgah Ave.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138735499

**Approval date**

2012-10-20, 1391/07/29

**Ethics committee reference number**

IR.MUMS.REC.1391.304

**Health conditions studied**

1

**Description of health condition studied**

plaque psoriasis lesions

**ICD-10 code**

L40

**ICD-10 code description**

Psoriasis

**Primary outcomes**

1

**Description**

Localized Psoriasis Severity Index

**Timepoint**

Before treatment and one week after the treatment is completed

**Method of measurement**

physical examination

**Secondary outcomes**

1

**Description**

Pigmentation

**Timepoint**

once a week in the course of treatment

**Method of measurement**

physical examination

2

**Description**

burning

**Timepoint**

once a week in the course of treatment

**Method of measurement**

physical examination

3

**Description**

redness  
**Timepoint**  
once a week in the course of treatment  
**Method of measurement**  
physical examination

## Intervention groups

### 1

#### Description

Intervention Group (blue light ): In the intervention group, the lesions will be treated by light emitted from Lightcure device for 15 minutes per session 3 times weekly for 4 consecutive weeks.

#### Category

Treatment - Other

### 2

#### Description

Control Group (topical steroid): In the control group, lesions will be treated by a moderate topical steroid (fluocinonolone ointment 0.1 percent) every eight hours for 4 consecutive weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dermatology Clinic of Ghaem Hospital

##### Full name of responsible person

Dr Pouran Layegh

##### Street address

Ahmadabad Ave.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138735499

##### Phone

+98 51 3844 9060

##### Email

LayeghPo@mums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Dermatology Clinic of Imam Reza Hospital

##### Full name of responsible person

Dr Masoud Maleki

##### Street address

Daneshgah Ave.

##### City

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##### Province

Razavi Khorasan

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9138735499

##### Phone

+98 51 3802 2000

##### Email

Maleki@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Mohsen Tafaghod

##### Street address

Daneshgah Ave.

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##### Province

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##### Phone

+98 51 3282 3255

##### Email

tafaghodim@mums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Zeinab Memarzadeh

##### Position

Resident of Dermatology

##### Latest degree

Medical doctor

##### Other areas of specialty/work

General Practitioner

##### Street address

Daneshgah Ave.  
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MemarzadehZ931@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Dr Pouran Layegh  
**Position**  
Dermatologist  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
General Practitioner  
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Daneshgah Ave.  
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LayeghPo@mums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Birjand University of Medical Sciences  
**Full name of responsible person**  
Mohammad Bagher Roozgar  
**Position**  
Translator  
**Latest degree**  
Master

### Other areas of specialty/work

Others  
**Street address**  
Ghaffari Ave.  
**City**  
Birjand  
**Province**  
South Khorasan  
**Postal code**  
9797153577  
**Phone**  
+98 56 3239 5680  
**Email**  
hadirooz@gmail.com

## 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

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

### Title and more details about the data/document

Deidentified Individual Participant Data Set will be provided in an excel file and provided on the research project website: <http://yon.ir/xzDIR>

### When the data will become available and for how long

when the study is completed and for 5 years

### To whom data/document is available

Those who refer to the project's website

### Under which criteria data/document could be used

Only for research purposes

### From where data/document is obtainable

the research website addressed at <http://yon.ir/xzDIR>

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

If a request is delivered via email, the deidentified data file will be sent within 10 days.

### Comments