

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Clinical trial of comparison of the efficacy of NBUVB phototherapy plus pioglitazone versus NBUVB phototherapy alone in the reduction of PASI score in patients with plaque type psoriasis

Protocol summary

Summary

Psoriasis is a chronic debilitating disease that can affect up to 2% of the population. Treatment with NBUVB is a well-recognized treatment for plaque type psoriasis. Pioglitazone is a thiazolidinedione insulin sensitizing agent that has shown to be an effective and safe treatment option in chronic plaque-type psoriasis. The underlying mechanism for this treatment is the anti proliferative, anti-inflammatory and anti angiogenic effects of pioglitazone. We have designed this randomized, double blind clinical trial to evaluate and compare the efficacy of a combination of NBUVB plus pioglitazone and NBUVB alone in the treatment of plaque type psoriasis. A total of 74 adult patients with plaque type psoriasis will be included and allocated randomly in to two groups. One group will be treated with NBUVB plus pioglitazone and the other group will be treated with NBUVB plus placebo. After 30 sessions of NBUVB the efficacy of treatment will be compared between groups in terms of the percentage of patients who achieve Psoriasis Area and Severity Index (PASI) 75. Improvement observed in PASI score will be documented and compared between two groups. The DLQI (Dermatology Life Quality Index) of the patients and adverse effects of treatment will also be compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091918607N2**

Registration date: **2017-02-28, 1395/12/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-28, 1395/12/10

Registrant information

Name

Maryam Ghiasi

Name of organization / entity

Tehran University of Medical Sciences, Department of Dermatology, Razi Hospital

Country

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+98 21 5561 8989

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-11-01, 1395/08/11

Expected recruitment end date

2017-11-01, 1396/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison of the efficacy of NBUVB phototherapy plus pioglitazone versus NBUVB phototherapy alone in the reduction of PASI score in patients with plaque type psoriasis

Public title

Evaluation of the efficacy of NBUVB (narrow band UVB)

phototherapy plus pioglitazone versus NBUVB
phototherapy alone in the treatment of plaque type
psoriasis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients with plaque type psoriasis;
indication of NBUVB phototherapy Exclusion criteria: age
under 18 years; treatment with phototherapy or systemic
drugs of psoriasis during the last 3 months; pregnancy;
lactation; congestive heart failure; renal diseases; liver
diseases; pulmonary diseases

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Ghods St, Keshavarz Blvd, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-10-25, 1395/08/04

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1395.856

Health conditions studied

1

Description of health condition studied

Psoriasis

ICD-10 code

L40.0

ICD-10 code description

Plaque psoriasis

Primary outcomes

1

Description

PASI 75

Timepoint

Before treatment and 10 weeks after starting treatment

Method of measurement

Examination

Secondary outcomes

1

Description

Dermatology Life Quality Index (DLQI)

Timepoint

Before treatment and 10 weeks after starting treatment

Method of measurement

Questionnaire

2

Description

Adverse effects

Timepoint

every month after starting treatment

Method of measurement

examination and asking from the patients

Intervention groups

1

Description

Pioglitazone group: NBUVB phototherapy three times a
week plus pioglitazone (tablet 30 mg, 1 tab/ day, oral)

Category

Treatment - Drugs

2

Description

Placebo group: NBUVB three times a week plus placebo
(the same as pioglitazone)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person
Street address
Razi Hospital, Vahdat Eslami Sq, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Masud Yunesian
Street address
Ghods St, Keshavarz Blvd, Tehran, Iran
City
Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty