

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 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

Iran (Islamic Republic of)

###### Phone

+98 21 5561 8989

###### Email address

mghiasi@tums.ac.ir

##### 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**  
Department of Dermatology, Tehran University of Medical Sciences  
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Maryam Ghiasi  
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## Person responsible for scientific inquiries

### Contact

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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*