

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Evaluation of the efficacy of Ursodeoxycholic acid plus methotrexate compared with methotrexate alone on faster improvement of patients with plaque-type psoriasis

#### Protocol summary

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

#### Summary

Psoriasis is a chronic inflammatory skin disease, and its treatment is very important due to psychological complications and disability. It involves approximately two to four percent of the world's population and has various clinical manifestations. In the most common type of the disease, it is characterized by scaly red plaques. Although the precisely molecular mechanisms of the disease are still largely unknown, but finding the biochemical mechanisms involved in its pathogenesis has played an important role in discovering new therapies and better control of the disease. One of the environmental triggers that initiates psoriasis is bacterial infection. Recent studies have shown the effect of anti-microbial activity for bile acids and decreasing microbial growth in the presence of high concentrations of bile acids has been reported. Several case-report studies have shown the efficacy of bile acids with a favorable safety profile when used in the treatment of patients suffering chronic plaque-type psoriasis. However, the use of Ursodeoxycholic acid for the treatment of psoriasis is still uncertain, therefore it is needed to develop a comprehensive study in this regard. If the beneficial effect of ursodeoxycholic acid in the treatment of patients with psoriasis is proven, then we can use it as an adjunct to the treatment of these patients. Ursodeoxycholic acid is relatively inexpensive and has limited side effects, so this will undoubtedly has a significant effect on accelerating the treatment process and reducing the cost of treatment for these patients.

Last update:

Update count: **0**

#### Registration date

2017-11-13, 1396/08/22

#### Registrant information

##### Name

Amine Kashiri

##### Name of organization / entity

Tehran university medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3232 7217

##### Email address

a-kashiri@razi.tums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2017-10-22, 1396/07/30

#### Expected recruitment end date

2018-06-21, 1397/03/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of the efficacy of Ursodeoxycholic acid plus methotrexate compared with methotrexate alone on faster improvement of patients with plaque-type

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017092536415N1**

Registration date: **2017-11-13, 1396/08/22**

psoriasis

### Public title

The efficacy of Ursodeoxycholic on faster improvement of patients with psoriasis

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion criteria: patients with psoriasis who are candidates for systemic therapy; they have not received systemic therapy as well as phototherapy for their disease during the past 6 months; they have not received topical treatment over the past month. Exclusion criteria: patients with history of heart failure, hepatic, renal and pulmonary disease or increase in liver function tests (More than 1.5 times normal), diabetes mellitus and other serious systemic disease; pregnant women; since the efficacy and safety of using Ursodeoxycholic acid in the pediatric population has not been established, this group will also be excluded from the study; People with a history of biliary disorders, and hypersensitivity to bile acids

### Age

From **15 years** old to **70 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **30**

### 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

Ethics Committee on Research in Tehran University of Medical Sciences

##### Street address

room 105, fifth floor, central building of Tehran University of Medical Sciences, Qods St, Keshavarz Blvd, Tehran, Iran

##### City

Tehran

### Postal code

1417653761

### Approval date

2017-09-10, 1396/06/19

### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.3405

## Health conditions studied

### 1

#### Description of health condition studied

Psoriasis

#### ICD-10 code

L40.0

#### ICD-10 code description

psoriasis vulgaris

## Primary outcomes

### 1

#### Description

Psoriasis area and severity index

#### Timepoint

Before intervention, two months after the intervention, six months after the intervention

#### Method of measurement

FotoFinder PASIvision

### 2

#### Description

Dermatology Life Quality Index

#### Timepoint

Before intervention, two months after the intervention, six months after the intervention

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

liver enzymes

#### Timepoint

Before intervention, two months after the intervention, six months after the intervention

#### Method of measurement

lab tests

### 2

#### Description

Serum lipid level

#### Timepoint

Before intervention, two months after the intervention, six months after the intervention

#### Method of measurement

lab tests

### 3

**Description**

Fatty liver

**Timepoint**

Before intervention, two months after the intervention, six months after the intervention

**Method of measurement**

Sonography

## Intervention groups

### 1

**Description**

Intervention group: taking capsules containing 300 mg of Ursudocysical colic acid once a day for six months

**Category**

Treatment - Drugs

### 2

**Description**

control group: taking placebo as a capsule of 300 mg once a day

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Razi Dermatology Hospital

**Full name of responsible person**

Dr Amine Kashiri ; Dermatology resident

**Street address**

Razi Dermatology Hospital, Islamic Unity square, Islamic Unity street, Tehran, Iran

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Mas'oud Younesian

**Street address**

Research Deputy of Tehran University of Medical Sciences, Central building of Tehran University of Medical Sciences, Qods intersection, 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Amine Kashiri

**Position**

Dermatology resident

**Other areas of specialty/work****Street address**

Razi Dermatology Hospital, Islamic Unity square, Islamic Unity street, Tehran, Iran

**City**

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**Postal code**

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**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr vahide Lajevardi

**Position**

assistant professor

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr Amine Kashiri  
**Position**  
Dermatology resident  
**Other areas of specialty/work**  
**Street address**  
Razi Dermatology Hospital, Islamic Unity square,  
Islamic Unity street, Tehran, Iran  
**City**  
Tehran  
**Postal code**  
1199663911  
**Phone**

## 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*