

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092536415N1**
Registration date: **2017-11-13, 1396/08/22**

Registration timing: **registered_while_recruiting**

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

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 candidated for systemic therapy; they have not received systemic therapy as well as phtotherapy for their disease during the past 6 month; they have not received topical treatment over the past month. Exclusion criteria: patients with history of heart failure, hepatic, renal and pulmonary disease or icreasement 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 Uroseodocyclic 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**

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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

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
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Other areas of specialty/work
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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