

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparative Effectiveness of Atorvastatin 5% lotion vs betamethasone lotion in treatment of seborrheic dermatitis in adult: Double blind Randomized Clinical trial study

Protocol summary

Summary

This study is a randomized, Without using a placebo-controlled, double-blind trial in 70 patients with seborrheic dermatitis aged 18 years to 65 years at dermatology clinic of hospital in Hamadan. After confirmation of seborrheic dermatitis by dermatologist and the same drug prescription, all patients will be randomly allocated into two groups according to randomly number tables. In one group, receive 5% of atorvastatin lotion daily with ketoconazole shampoo 3 times a week for 4 weeks, and the other group receive betamethasone lotion 3 times a week with ketoconazole shampoo 3 times a week. Severity of clinical symptoms are determined in all patients using the recommended Koca scoring system at the earliest stages of treatment, 2 weeks, 4 weeks, and 4 weeks after the end of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070922965N11**

Registration date: **2017-07-18, 1396/04/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-18, 1396/04/27

Registrant information

Name

Maryam Mehrpoya

Name of organization / entity

School of Pharmacy, Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ethics Committee of Hamadan University of Medical Sciences

Expected recruitment start date

2017-08-06, 1396/05/15

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effectiveness of Atorvastatin 5% lotion vs betamethasone lotion in treatment of seborrheic dermatitis in adult: Double blind Randomized Clinical trial study

Public title

Effect of topical atorvastatin in seborrheic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Patients with seborrheic dermatitis in the scalp and face with clinical diagnosis: Lack of treatment with topical or systemic corticosteroids. Methyl dopa. Chlorpromazine. Topical or systemic acne medications from a month before referral: Failure to develop a systemic disorder, such as Parkinson's

disease, AIDS, mood disorders. exclusion criteria:Report any allergy to the drug, such as Contact dermatitis:Dissatisfaction with drug use and collaborative study:Lack of referral for follow up and observation of the therapeutic efficacy of the drug:Having a very severe type of disease(Itching score greater than 7):Pregnancy and lactation

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Khajerashid,Ayatollah Kashani,Hamadan University of Medical Sciences

City

Hamadan

Postal code**Approval date**

2017-07-08, 1396/04/17

Ethics committee reference number

IR.UMSHA.REC.1396.310

Health conditions studied**1****Description of health condition studied**

seborrheic dermatitis

ICD-10 code

L21.8

ICD-10 code description

Other seborrheic dermatitis

Primary outcomes**1****Description**

seborrheic dermatitis

Timepoint

2 and 4 weeks following of treatment and 4 weeks after the end of treatment.

Method of measurement

Koca scoring system

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: ketoconazole shampoo three times a week with 5% atorvastatin lotion daily

Category

Treatment - Drugs

2**Description**

Control group: ketoconazole shampoo 3 times a week with betamethasone lotion daily

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Farshchian Hospital

Full name of responsible person**Street address****City**

Hamadan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

vice chancellor for research,Hamadan University of Medical Sciences

Full name of responsible person

Alireza Ahmadi

Street address

Hamadan University of Medical Sciences ,Shahid Fahmide avenue ,Hamadan

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

vice chancellor for research,Hamadan 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

School of Pharmacy,Hamadan University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

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