

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Evaluation of effectiveness of betamethasone lotine 0/1% compared with clotrizone lotion (clotrimazole1% and betamethasone 0/05%) in patients with seborrheic dermatitis of face and scalp

#### Protocol summary

##### Summary

The aim of this study is to evaluate the effect of topical betamethasone lotion 0/1% compared with clotrizone lotion (clotrimazole1% and betamethasone 0/05%) in patients with seborrheic dermatitis of face and scalp referred to Quaem and Emam Reza dermatology clinic, after filling council form randomly will be treated with betamethasone lotion or clotrizone lotion. Our method will be block randomization. All drugs in one pharmacy and with similar bottle with numerical code will be prepared. Patients and physician will be blind about kind of treatment. Instruction is topical use of lotion in symptomatic area twice a day for one month. Severity of disease will be obtained with SDASI. According to this method patients will be examined in first visit and in 2 and 4 week after beginning of treatment and severity of disease will be recorded. Examination will be repeated 4 and 8 week after end of treatment period to evaluate the rate of recurrence.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016060628291N1**

Registration date: **2016-06-20, 1395/03/31**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-06-20, 1395/03/31

##### Registrant information

###### Name

Seyedeh Fatemeh Yaghoobi Al

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3801 2493

###### Email address

sfya@rayana.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research of Hamedan University of Medical Sciences

##### Expected recruitment start date

2016-06-21, 1395/04/01

##### Expected recruitment end date

2017-06-22, 1396/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of effectiveness of betamethasone lotine 0/1% compared with clotrizone lotion (clotrimazole1% and betamethasone 0/05%) in patients with seborrheic dermatitis of face and scalp

##### Public title

Evaluation of effectiveness of betamethasone lotine 0/1% compared with clotrizone lotion (clotrimazole1% and betamethasone 0/05%) in patients with seborrheic dermatitis of face and scalp

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients more than 18 years old with

seborrheic dermatitis of face and scalp referred to Quaem and Emam Reza dermatology clinics. Exclusion Criteria: Patient with systemic disease; Use of topical or systemic treatments of seborrheic dermatitis during 2 previous weeks; Pregnancy and lactation; History of allergy to the drugs of this study; HIV infection; Parkinson disease; Using of psychiatric drugs; Other papulo squamous disease (psoriasis, tinea,...).

#### Age

From **18 years** old to **70 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

#### 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 of Hamedan University of Medical Sciences

##### Street address

Mahdieh Street, Hamedan University of Medical Sciences

##### City

Hamedan

##### Postal code

#### Approval date

2015-06-20, 1394/03/30

#### Ethics committee reference number

IR.UMSHA.REC.1394.174

## Health conditions studied

### 1

#### Description of health condition studied

Seborrheic dermatitis

#### ICD-10 code

L21

#### ICD-10 code description

Seborrheic dermatitis

## Primary outcomes

### 1

#### Description

Improvement of erythema scaling and pruritus

#### Timepoint

2 and 4 weeks after beginning of treatment and 4 and 8 weeks after end of treatment period

#### Method of measurement

Based on measuring the change of amount of erythema scaling and pruritus

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Betamethasone lotine 0/1% Made in Iran Najo 20 m, 20 ml, twice a day for month in Symptomatic section

#### Category

Treatment - Drugs

### 2

#### Description

Clotrizone lotion (clotrimazole1% and betamethasone 0/05%) Made in Iran Najo 20 ml, twice a day for month in Symptomatic section

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dermatology clinic, Quaem Hospital

##### Full name of responsible person

Seyedeh Fatemeh Yaghoubi Al

##### Street address

Department of dermatology, Quaem hospital, Ahmad Abad Street

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of Hamedan University of Medical Sciences

**Full name of responsible person**

Dr saeid Bashirian

**Street address**

Mahdieh Street, Hamedan University of Medical Sciences

**City**

Hamedan

**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 of Hamedan 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Seyedeh Fatemeh Yaghoubi Al

**Position**

Resident

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

Dermatology clinic, Quaem hospital, Ahmad Abad Street

**City**

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**Fax****Email**

sfya@rayana.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Seyedeh Fatemeh Yaghoubi Al

**Position**

Resident of dermatology

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

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Mashhad University of Medical Sciences

**Full name of responsible person**

Akram Sadat Momenzadeh

**Position**

Bachelor of Biology

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

Cutaneous Leishmaniasis Research Center, Mashhad University of Medical Sciences

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**Web page address****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*