Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The comparision study of sertaconazole 2% cream versus pimecrolimus 1% cream in the treatment of facial seborrheic dermatitis

Protocol summary

Summary

The aim of this study is to compare the efficacy of two non steroidal creams, sertaconazole cream 2% with pimecrolimus cream 1%, in the treatment of seborrheic dermatitis. Adulthood patients with face seborrhoeic dermatitis (frontal hair line, eyebrows, forehead gellabella area, nasolabial folds and or anterior auricular regions) with no systemic disease will enroll. The cases are the patients who will visit by a dermatologist in clinics or offices of Semnan city of Iran. The diagnosis of disease will be clinically. Sixty patients with seborrhoeic dermatitis are selected and will be divided randomly into two equal groups. This study will take six months. The patients will apply one of two drugs, twice a day for four weeks. The patients will be visited by a dermatologist (blind to type of drug) in 0, 2, 4, 8 weeks of starting treatment and will get a special score in each visit. The scoring will be base on the severity of erythema, scaling, itching , and burning sensation of damage area, which are rated from 0-3 (0 = absent , 1 = mild , 2 = moderate , 3 = severe). The sum of these values shows the severity of disease (0-4= mild, 5-8= moderate, 9-12=severe) Moreover, patient's satisfaction will be asked and recorded at the end of weeks 2 and 4 of treatment as below: No, weak, medium or good improvement. The score of 8 weeks of starting treatment will show the probable relapse.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041613853N1**
Registration date: **2014-04-16, 1393/01/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-04-16, 1393/01/27

Registrant information

Name

Maryam Azizzadeh

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research - Semnan University of Medical Science

Expected recruitment start date

2014-04-01, 1393/01/12

Expected recruitment end date

2014-10-01, 1393/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparision study of sertaconazole 2% cream versus pimecrolimus 1% cream in the treatment of facial seborrheic dermatitis

Public title

The comparision of sertaconazole versus pimecrolimus in the treatment of facial seborrheic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria
inclusion criteria: facial seborrheic dermatitis; any systemic disease. exclusion criteria: taking drugs such as methyldopa, chlorpromazine, cimetidine; use of local and systemic anti-acne ,steroid and immune modulators drugs one month before; lactation and pregnancy.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Semnan university of medical science
Street address
Basij Blvd.
City
Semnan
Postal code
Approval date
2013-11-27, 1392/09/06
Ethics committee reference number
10900-16-92

Health conditions studied

1

Description of health condition studied
Seborrheic dermatitis (SD)
ICD-10 code
L21
ICD-10 code description
Seborrhoeic dermatitis

Primary outcomes

1

Description
improvment
Timepoint
2 and 4 weeksafter starting treatment
Method of measurement
dermatologist examination

2

Description
exacerbation
Timepoint
1 month after stoping treatment
Method of measurement
dermatologist examination

3

Description
treatment duration
Timepoint
4 weeks
Method of measurement
time

4

Description
patient satisfaction
Timepoint
2 and 4 weeks after starting treatment
Method of measurement
question of patient

Secondary outcomes

1

Description
side effect
Timepoint
2 and 4 weeks after starting treatment
Method of measurement
dermatologist examination

Intervention groups

1

Description
Topical pimecrolimus cream 1% will be given to the 30 patients. They will be recommended to use tip finger amount of cream to each involved area, 2 times daily for 4 weeks. The Patients will be visited by a dermatologist (who is blind to the type of drug) on zero, 2, 4 and 8 weeks of starting treatment, in order to evaluate the clinical symptoms and complications.
Category

Treatment - Drugs

2

Description

Topical sertaconazole cream 2% will be given to the 30 patients. They will be recommended to use tip finger amount of cream to each involved area, 2 times daily for 4 weeks. The Patients will be visited by a dermatologist (who is blind to the type of drug) on zero, 2, 4 and 8 weeks of starting treatment, in order to evaluate the clinical symptoms and complications.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic

Full name of responsible person

Dr. Maryam Azizzadeh

Street address

17 e shahrivar blvd.

City

Semnan

2

Recruitment center

Name of recruitment center

Kowsar hospital

Full name of responsible person

Dr. Maryam Azizzadeh

Street address

Basij Blvd.

City

Semnan

3

Recruitment center

Name of recruitment center

Dermatology office

Full name of responsible person

Dr. Maryam Azizzadeh

Street address

No.2, Third floor, Sadaf building, Saadi square

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research -Semnan University of Medical Science

Full name of responsible person

Dr. mohammadreza Askari

Street address

Basij Blvd.

City

Semnan

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 -Semnan University of Medical Science

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

Semnan University of Medical Science

Full name of responsible person

Maryam Azizzadeh

Position

Dermatologist

Other areas of specialty/work

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Position

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Other areas of specialty/work

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Other areas of specialty/work
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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