

Comparison of the efficacy of pimecrolimus 1% cream and hydrocortisone 1% cream in facial seborrheic dermatitis: a single-blind randomized clinical trial

Submission date

22/01/2005

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

19/04/2005

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

15/02/2008

Condition category

Skin and Connective Tissue Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

Pimecrolimus 1% cream improves facial seborrheic dermatitis better than hydrocortisone 1% cream

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Seborrheic dermatitis

Interventions

Group 1: pimecrolimus 1% cream applied twice daily for 2 weeks

Group 2: hydrocortisone acetate 1% cream applied twice daily for 2 weeks

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Pimecrolimus, hydrocortisone

Primary outcome measure

1. Clinical response (erythema, pruritis, scaling) at 2, 4 and 6 weeks after treatment
2. Patient's general perception about treatment result
3. Adverse events in each treatment group

Secondary outcome measures

Not provided at time of registration

Overall study start date

20/01/2005

Completion date

31/07/2005

Eligibility

Key inclusion criteria

Patients with facial seborrheic dermatitis older than 8 years.

Participant type(s)

Patient

Age group

Child

Lower age limit

8 Years

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Presence of active malignancy on the facial lesion
2. Presence of any kind of active viral skin disease on the facial lesion
3. Use of oral steroids in the past two weeks
4. Use of psoralen plus ultraviolet A (PUVA), ultraviolet B (UVB), ultraviolet A (UVA), azathioprine or cyclosporin in past month
5. Application of any topical treatment in past week
6. Use of any systemic antibiotics or antifungals in past 2 weeks
7. Attending in any other research study

Date of first enrolment

20/01/2005

Date of final enrolment

31/07/2005

Locations

Countries of recruitment

Iran

Study participating centre

79 Taleghani Avenue

Tehran

Iran

14166

Sponsor information

Organisation

Tehran University of Medical Sciences (Iran) - Center for Research and Training in Skin Diseases and Leprosy

Sponsor details

79 Taleghani Avenue

Tehran

Iran

14166

Sponsor type

Hospital/treatment centre

Website

<http://www.tums.ac.ir/english/>

ROR

<https://ror.org/01c4pz451>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Tehran University of Medical Sciences (Iran) - Center for Research and Training in Skin Diseases and Leprosy

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/08/2006		Yes	No