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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

Registration date
19/04/2005

Overall study status
Completed

Last Edited
15/02/2008

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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