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Excimer laser versus clobetasone propionate in prurigo form of atopic dermatitis

Submission date	Recruitment status
28/12/2006	No longer recruiting
Registration date	**Overall study status**
28/12/2006	Completed
Last Edited	**Condition category**
14/01/2021	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
NL785, NTR797

Study information

Scientific Title
Excimer laser versus clobetasone propionate in prurigo form of atopic dermatitis

Study objectives
As Narrow Band UltraViolet B (NB-UVB) is known to be effective in Atopic Dermatitis (AD), the excimer laser appears to be a promising treatment for localised AD. We designed a randomised single blind within-patient controlled trial to investigate the efficacy of the excimer laser versus routine topical corticosteroid, clobetason propionate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval recieved from the Medical Ethical Committee (Medisch Ethische Commissie) on the 19th October 2006 (ref: MEC 06/239).

Study design
Randomised, controlled, parallel group, single blind, trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Atopic dermatitis

Interventions
All patients will be randomised to a within-patient left-right comparison study of excimer laser versus topical clobetason propionate. Treatment with the ecximer laser will be performed twice a week, during a treatment period of ten weeks. Clobetason propionate will be applied by the patients themselves once a day , according standardised instructions, during a treartment period of ten weeks.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Clobetasol propionate

Primary outcome measure
Clinical responses will be evaluated using physician assessment of individual signs (number of nodules, elevation of nodules, excoriation, erythema and pruritus).

Secondary outcome measures
1. Photographic documentation
2. Physician Global Assessment (PGA)
3. Patient Global Assessment (PaGA)
4. Besides the clinical responses, the patient and physician satisfaction/preference and duration of remission will be evaluated.

Overall study start date
01/11/2006

Completion date
01/08/2007

Eligibility

Key inclusion criteria
1. Adult patients (over 18 years old)
2. Prurigo form of atopic dermatitisbased on:
a. Hanifin and Rajka criteria fullfilled
b. presence of allergen specific Immunoglobulin E (IgE)
c. lasting for at least six months
d. refractory to the standard therapy
e. at least four symmetrical nodules
3. Upper or lower extremities affected
4. Written informed consent provided

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
20

Total final enrolment
13

Key exclusion criteria
1. Patients unable to comply with the requirements of the study
2. Female patients who are pregnant or breastfeeding
3. Patients treated with sedating antihistamines within 24 hours before start of study treatment
4. Patients treated with topical steroids within one week before start of study treatment
5. Patients treated with phototherapy or Psoralen UltraViolet A (PUVA) therapy within one week before start of study treatment
6. Patients treated with systemic therapy that might have an effect on the prurigo form of AD within four weeks before start of study treatment
7. Patients with hypersensitivity to the study treatment or sunlight
8. Patients receiving drugs known to cause photosensitivity and/or photo toxicity
9. Patients with any other interfering skin diseases, which jeopardize the study

Date of first enrolment
01/11/2006

Date of final enrolment
01/08/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center Amsterdam
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

Sponsor details
Department of Dermatology
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/#http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Center (AMC) (The Netherlands)

Alternative Name(s)
Academic Medical Center, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

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	01/10/2010	14/01/2021	Yes	No