Excimer laser versus clobetasone propionate in prurigo form of atopic dermatitis

Submission date	Recruitment status	Prospectively registered		
28/12/2006	No longer recruiting	Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/12/2006	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
14/01/2021	Skin and Connective Tissue Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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 treatment period of ten weeks.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Clobetasol propionate

Primary outcome(s)

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

Key secondary outcome(s))

- 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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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)

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)

LocationNetherlands

Results and Publications

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