Excimer laser versus clobetason propionaat in prurigo form of atopic dermatitis.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29170

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Prurigo form of atopic dermatitis

Sponsors and support

Primary sponsor: Academic Medical Center, University of Amsterdam, Dept. of Dermatology

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Photographic documentation, Physician Global assessment (PGA) and Patient Global Assessment (PaGA) will be evaluated. Besides the clinical responses, the patient and physician satisfaction/preference and duration of remission will be evaluated.

Study description

Background summary

Background:

(UVB) phototherapy is widely recognised as effective treatment modality for patients with chronic atopic dermatitis (AD). Recent findings establish the 308 xenon chloride (XeCl) excimer laser to be a new option in the area of UVB phototherapy. The XeCl excimer laser enables large fluences of narrow-band (NB) UVB and precise targeting of effected skin. As NB-UVB is known to be effective in AD, the excimer laser appears to be a promising treatment for localized AD.

Objectives:

Primary, to investigate the efficacy of XeCl excimer laser therapy versus topical corticosteroid in a side-to-side comparison in patients with the prurigo form of AD. Secondary, to assess the duration of remissions achieved with excimer laser and to evaluate the patient¡¯s and investigator¡¯s satisfaction/preferences regarding both treatments.

Study design:

Prospective single blind randomised within-patient controlled study.

Patients and methods:

Adult patients > 18 years diagnosed with a prurigo form of AD at the Depatment of Dermatology of the AMC, who meet the inclusion criteria, will be included. All patients will be randomized to a within-patient left-right comparison study of excimer laser versus topical clobetason propionaat. Treatment with the ecximer laser will be performed twice a week, during a treatment period of 10 weeks, Clinical responses will be evaluated using Physician Assessment of Individual Signs (PAIS) (number of nodules, elevation of nodules, excoriation, erythema and pruritus), photographic documentation, Physician Global assessment (PGA) and Patient Global Assessment (PaGA). Besides the clinical responses, the patient and physician satisfaction/preference and duration of remission will be evaluated.

Study objective

As NB-UVB is known to be effective in AD, the excimer laser appears to be a promising treatment for localized AD. We designed a randomized single blind within-patient controlled trial to investigate the efficacy of the excimer laser versus routine topical corticosteroid, clobetason propionaat.

Study design

N/A

Intervention

All patients will be randomized to a within-patient left-right comparison study of excimer laser versus topical clobetason propionaat. Treatment with the ecximer laser will be performed twice a week, during a treatment period of 10 weeks. Clobetason propionaat will be applied by the patients themselves once a day , according standardised instructions, during a treartment period of 10 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Adult patients (>18 years old);

2. Prurigo form of atopic dermatitisbased on:

2.1 Hanifin and Rajka criteria fullfilled;

2.2 Presence of allergen specific IgE;

2.3 Lasting for at least 6 months;

2.4 Refractory to the standard therapy;

2.5 At least 4 symmetrical nodules;

3. Upper or lower extremities affected;

4. Written informed consent provided.

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 24hrs 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 PUVA 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 4 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2006
Enrollment:	20
Type:	Actual

Ethics review

Positive opinion

Date:	19-09-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL785
NTR-old	NTR797
Other	: N/A
ISRCTN	ISRCTN38773821

Study results

Summary results
N/A