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

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| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON29170

**Bron**
NTR

**Verkorte titel**
N/A

**Aandoening**

Prurigo form of atopic dermatitis

### Ondersteuning

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

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

**Onderzoeksopzet**

N/A

**Onderzoeksproduct en/of interventie**

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.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 01-11-2006 |
| Aantal proefpersonen: | 20 |
| Type: | Werkelijke startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 19-09-2006 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL785 |
| NTR-old | NTR797 |
| Ander register | : N/A |
| ISRCTN | ISRCTN38773821 |

# Resultaten

**Samenvatting resultaten**
N/A