Study of the efficacy of topically applied cyclosporinsolution on psoriatic nails.

Gepubliceerd: 23-06-2006 Laatst bijgewerkt: 18-08-2022

N/A

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

Samenvatting

ID

NL-OMON25326

Bron
NTR

Verkorte titel
N/A

Aandoening

Psoriasis of the vingernails.

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: novartis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

NAPSI scores.

Toelichting onderzoek

Achtergrond van het onderzoek

The aim of the study is to establish and evaluate the affectivity of topical application of cyclosporine in psoriasis of the fingernails.

Patients with psoriasis of fingernails presenting at the outpatient department of Dermatology Erasmus MC. The patients receive 2 identical bottles, one for the left and one for the right hand to take home. One bottle contains cyclosporine solution (Neoral drink) and the other contains
maize oil. The patients apply the solution to the affected nails and nail wall with an applicator (small brush) twice a day. The duration of the treatment is till complete cure or for a maximum of 16 weeks. The follow-up is for 12 weeks after stopping the treatment.

The nail abnormality is photographed before the start of the treatment.

The nail psoriasis severity index (NAPSI) is calculated for the affected nails on each visit. This will also serve for further follow-up.

Doel van het onderzoek

N/A

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

On left and right vingernails either placebo, either 100mg/ml ciclosporin application, twice daily.

The duration of the treatment is till complete cure or for a maximum of 16 weeks.

Control group maximal 28 weeks.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Clinical diagnosis of psoriasis of fingernails in both hands;

2. In cases of oral treatment with methotrexate, prednisone or fumarates, the dose of medication before the start has to be constant for 8 weeks and it may be reasonably expected that the dose shall not be altered during the treatment phase of the study;

3. A minimum of at least 2 affected nails on the left hand and the right hand, and the number of affected nails may differ by 1 nail at the maximum on the left hand compared with those on the right hand.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Systemic treatment with cyclosporine or a biological agent (efaluzimab, etanercept or related medication);

2. Change of oral medication 8 weeks before the start of the trial;

3. Pregnancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2006
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	23-06-2006
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	NL705
NTR-old	NTR715
Ander register	: N/A
ISRCTN	ISRCTN47031769

Resultaten

Samenvatting resultaten
N/A