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

No registrations found.

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

Summary

ID

NL-OMON25326

Source
NTR

Brief title
N/A

Health condition

Psoriasis of the vingernails.

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: novartis

Intervention

Outcome measures

Primary outcome

NAPSI scores.

Secondary outcome

Prevention? Does the NAPSI correlate with patientsatisfaction?

Study description

Background summary

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.

Study objective

N/A

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2006
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	23-06-2006
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	NL705

Register	ID
NTR-old	NTR715
Other	: N/A
ISRCTN	ISRCTN47031769

Study results

Summary results
N/A