

Study of the efficacy of topically applied cyclosporin solution on psoriatic nails

Submission date 26/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 10/03/2008	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Psoriatic nails

Interventions

On left and right fingernails either placebo, or 100 mg/ml cyclosporin application, twice daily.
The duration of the treatment is till complete cure or for a maximum of 16 weeks.
Control group maximal 28 weeks

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cyclosporin

Primary outcome measure

Nail Psoriasis Severity Index (NAPSI) scores.

Secondary outcome measures

1. Prevention
2. Does the NAPSII correlate with patient satisfaction

Overall study start date

01/07/2006

Completion date

01/07/2006

Eligibility

Key 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 eight 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 two affected nails on the left hand and the right hand, and the number of affected nails may differ by one nail at the maximum on the left hand compared with those on the right hand

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Systemic treatment with cyclosporine or a biological agent (efaluzimab, etanercept or related medication)
2. Change of oral medication eight weeks before the start of the trial
3. Pregnancy

Date of first enrolment

01/07/2006

Date of final enrolment

01/07/2006

Locations

Countries of recruitment

Netherlands

Study participating centre
Postbus 2040
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation
Erasmus Medical Center (The Netherlands)

Sponsor details
P.O. Box 2040
Rotterdam
Netherlands
3000 CA

Sponsor type
Hospital/treatment centre

ROR
<https://ror.org/018906e22>

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharma B.V. (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration