ISRCTN47031769 https://doi.org/10.1186/ISRCTN47031769

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

Submission date	Recruitment status	[_] Prospectively registered
26/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/03/2008	Skin and Connective Tissue Diseases	[_] 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 NAPSI 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
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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