

Myfortic® versus Neoral® as long-term treatment in patients with severe atopic dermatitis: a randomised-controlled trial

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 20/12/2005	Overall study status Completed	☐ Protocol
Last Edited 13/10/2008	Condition category Skin and Connective Tissue Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr I Haeck

Contact details

University Medical Center Utrecht
Department of Dermatology, HPN G02.124
Postbus 85500
Utrecht
Netherlands

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+31 (0)30 250 7388
I.Haek@umcutrecht.nl

Additional identifiers

Protocol serial number

NTR329

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised, active controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Atopic dermatitis

Interventions

After initial treatment of 6 weeks with Neoral® 5 mg/kg for all patients, there is a randomisation in two groups. One group is treated with Neoral® 3 mg/kg and the other group with Myfortic® 1440 mg.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Myfortic®, Neoral®

Primary outcome(s)

Clinical severity score (Local Levery Score [LSS])

Key secondary outcome(s)

1. Physician Global Assessment Score (PGA)
2. Serum levels of thymus and activation and regulated chemokine (TARC)
3. Itch (Visual Analogue Score [VAS])
4. Amount of topical steroids that is used
5. Quality of life, measured with the Dermatology Life Quality Index (DLQI) of Finlay

Completion date

01/09/2007

Eligibility

Key inclusion criteria

1. Aged from 18 years
2. Atopic dermatitis according to the criteria of Hanifin and Rajka
3. Insufficient response to topical treatment alone
4. The physician estimates that treatment with oral immunosuppressive agents is indicated

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Oral immunosuppressive treatment in the last 6 weeks
2. Concomitant ultraviolet (UV) therapy
3. Patients with any known hypersensitivity to cyclosporine (Neoral®) or mycophenolic acid (myfortic®) or other components of the formulation (e.g. lactose)
4. Patients with thrombocytopenia (less than $75000/\text{mm}^3$), with an absolute neutrophil count of less than $1500/\text{mm}^3$ and/or leukocytopenia (less than $2500/\text{mm}^3$), and/or haemoglobin less than 60 g/dL prior to enrolment
5. Patients who have received an investigational drug within two weeks prior to screening (i.e. before day 14 of run-in period)
6. Patients with a history of malignancy within the last five years
7. Females of childbearing potential who are planning to become pregnant, who are pregnant and/or lactating, who are unwilling to use effective means of contraception
8. Presence of clinically significant infection requiring continued therapy, severe diarrhoea, active peptic ulcer disease, or uncontrolled diabetes mellitus that would interfere with the appropriate conduct of the study
9. Known positive human immunodeficiency virus (HIV)
10. Evidence of drug and/or alcohol abuse

Date of first enrolment

01/09/2005

Date of final enrolment

01/09/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Utrecht

Utrecht

Netherlands

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Sponsor information

Organisation

University Medical Centre Utrecht (UMCU) (Netherlands)

ROR

<https://ror.org/04pp8hn57>

Funder(s)

Funder type

Industry

Funder Name

Novartis Pharma B.V. (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration