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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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
13/10/2008

Condition category
Skin and Connective Tissue Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] 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
-
+31 (0)30 250 7388
I.Haeck@umcutrecht.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Randomised, active controlled, parallel group 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
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 measure
Clinical severity score (Local Leverity Score [LSS])

Secondary outcome measures
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

Overall study start date
01/09/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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/mm^3), with an absolute neutrophil count of less than 1500/mm^3 and/or leukocytopenia (less than 2500/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
-

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (Netherlands)

Sponsor details
PO Box 85500
Utrecht
Netherlands
3508 GA

Sponsor type
University/education

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

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