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

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON24713

**Source**
NTR

**Brief title**
N/A

### Intervention

### Outcome measures

#### Primary outcome

Clinical severity score: LSS.

#### Secondary outcome

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.

# Study description

### Background summary

N/A

### Study objective

N/A

### Study design

N/A

### Intervention

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

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Age 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.

## Exclusion criteria

1. Oral immunosuppressive treatment in the last 6 weeks;

2. Concomitant 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 (< 75.000/mm3), with an absolute neutrophil count of < 1.500/mm3 and/or leukocytopenia (< 2.500/mm3), and/or haemoglobin < 6.0 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 diarrhea, active peptic ulcer disease, or uncontrolled diabetes mellitus that would interfere with the appropriate conduct of the study;

9. Known positive HIV;

10. Evidence of drug and/or alcohol abuse.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |

**Control:** Active

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-09-2005 |
| Enrollment: | 40 |
| Type: | Actual |

# Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

# 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 | NL291 |
| NTR-old | NTR329 |
| Other | : N/A |
| ISRCTN | ISRCTN70446233 |

# Study results

**Summary results**
N/A