

Phase III Clinical Trials in New Onset Juvenile Dermatomyositis: Steroids Treatment versus Steroids plus Cyclosporine Treatment versus Steroids plus Methotrexate Treatment.

No registrations found.

| | |
|------------------------------|----------------|
| Ethical review | Not applicable |
| Status | Recruiting |
| Health condition type | - |
| Study type | Interventional |

Summary

ID

NL-OMON23726

Source

NTR

Brief title

Clinical Trial in New Onset Juvenile Dermatomyositis

Health condition

Newly onset juvenile dermatomyositis patients.

Sponsors and support

Primary sponsor: no commercial sponsoring. International organisation is PRINTO (pediatric rheumatology International trials organisation)

Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Time to clinical remission.

Secondary outcome

1. Change over time in the clinical core set parameters (PRINTO core set for JDM);
2. Time to muscle enzyme normalisation;
3. Frequency of drop out due to ineffective treatment.

Study description

Background summary

N/A

Study objective

Combination therapy of steroids plus MTX induces remission faster and will therefor reduce steroid toxicity and disease damage.

Study design

N/A

Intervention

Randomisation into 3 groups:

1. Standard therapy steroids only;
2. Steroids plus methotrexate;
3. Steroids plus ciclosporin.

Contacts

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Eligibility criteria

Inclusion criteria

1. Newly onset juvenile dermatomyositis;
2. Patients aged <18 years;
3. Negative pregnancy test;
4. Obtained informed consent;
5. Ability to comply.

Exclusion criteria

1. Neutropenia;
2. Failure to comply;

3. Ulcerations, cardio-pulmonary disease related to juv dermatomyositis.

Study design

Design

| | |
|---------------------|-----------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

Recruitment

| | |
|---------------------------|-------------|
| NL | |
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-06-2006 |
| Enrollment: | 160 |
| Type: | Anticipated |

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

NTR-new

NTR-old

Other

ISRCTN

ID

NL609

NTR667

: N/A

Incomplete info for ISRCTN

Study results

Summary results

N/A