

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

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	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

### Public

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### Scientific

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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

<b>Register</b>	<b>ID</b>
NTR-new	NL609
NTR-old	NTR667
Other	: N/A
ISRCTN	Incomplete info for ISRCTN

## Study results

### Summary results

N/A