

# Dexa-Myositis Trial.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25817

### Source

NTR

### Brief title

N/A

### Health condition

polymyositis, dermatomyositis, myositis with rheumatological disorders, myositis with cancer, unspecified myositis

## Sponsors and support

**Source(s) of monetary or material Support:** Prinses Beatrix Fonds

## Intervention

## Outcome measures

### Primary outcome

1. Combined scale:

Rankin, muscle strength, VAS pain, time untill remission, no relaps, no cushing, no osteoporosis;

2. Percentage patients in remission, time to remission, no relapse;

3. General assessment of condition of patients.

### **Secondary outcome**

1. Weight;
2. Bloodpressure;
3. VAS arthralgia, Raynaud;
4. Skin changes;
5. CK;
6. Myometry;
7. VAS dysfagia;
8. VAS agitation;
9. Quality of life;
10. Medication and dose;
11. Other side effects;
12. Neuromuscular symptom score.

## **Study description**

### **Background summary**

Is the treatment with dexamethasone pulse therapy safer and as good as or better than the treatment with prednisone in patients with polymyositis, dermatomyositis, myositis with rheumatological disease, myositis with cancer or unspecified myositis.

80 patients will participate in the multicentre randomized controlled trial.

### **Study objective**

Dexamethasone pulse therapy is safer and as good as/or better than treatment with prednisone in patients with myositis.

### **Intervention**

Dexamethasone pulse therapy. 40 mg/dag every first four days of the month, for 6 months. Placebo on the other days of the months.

2. Prednisolone 1-1.5 mg/kg/day for 4 weeks, after this slow reduction in dose.

Both groups treatment against osteoporosis with calci chew and fosamax.

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

1. Polymyositis;
2. Dermatomyositis;
3. Myositis with rheumatological disorders;
4. Myositis with cancer;
5. Unspecified myositis.

## Exclusion criteria

1. Myositis in family;
2. 3/1000 rimmed vacuoles;
3. Quick (<2 weeks) rise and spontaneous normalisation (<2 months) of serum CK level;
4. Age < 18 years;
5. Contra-indication for one of the two treatments;
6. Desire to get pregnant or active pregnancy;
7. No Informed Consent;
8. 20 mg prednisone/day.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-07-2001
Enrollment:	80
Type:	Anticipated

## Ethics review

Positive opinion

Date: 30-08-2005  
Application type: First submission

## 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	NL135
NTR-old	NTR169
Other	: N/A
ISRCTN	ISRCTN48188950

## Study results

### Summary results

N/A