Dexa-Myositis Trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25817

Source
Nationaal Trial Register

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. Neuromusclular symptom score.

Study description

Background summary

Is the treatment with dexamethasone pulse therapy saver and as good as or better than the treatment with prednisone in patients with polymyositis, dermatomyositis, myositis with rheumatological disease, myositis with cancer or unspecifiek myositis.
80 patients will participate in the multicentre randomized controlled trial.

Study objective

Dexamethason pulse therapy is saver 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, afther this slow reduction in dose.

Both groups treatment agains osteoporosis with calci chew and fosamax.

Contacts

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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