

Dexa-Myositis Trial: treatment of polymyositis and dermatomyositis - dexamethasone versus prednisone

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 20/12/2005	Overall study status Completed	☐ Protocol
Last Edited 16/09/2008	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

NTR169

Study information

Scientific Title

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Multicentre, randomised, double blinded, active controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Myositis, dermatomyositis, polymyositis

Interventions

1. Dexamethasone pulse therapy. 40 mg/day 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.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Dexamethasone, prednisone

Primary outcome(s)

1. Combined scale: Rankin, muscle strength, Visual Analogue Scale (VAS) pain, time until remission, no relapse, no cushing, no osteoporosis
2. Percentage patients in remission, time to remission, no relapse
3. General assessment of condition of patients

Key secondary outcome(s)

1. Weight
2. Blood pressure
3. VAS arthralgia, Raynaud
4. Skin changes
5. CK

6. Myometry
7. VAS dysphagia
8. VAS agitation
9. Quality of life
10. Medication and dose
11. Other side effects
12. Neuromuscular symptom score

Completion date

01/01/2008

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

1. Myositis in family
2. Greater than 3/1000 rimmed vacuoles
3. Quick (less than 2 weeks) rise and spontaneous normalisation (less than 2 months) of serum creatine kinase (CK) level
4. Aged less than 18 years
5. Contra-indication for one of the two treatments
6. Desire to get pregnant or active pregnancy
7. No informed consent
8. Greater than 20 mg prednisone/day

Date of first enrolment

01/07/2001

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Academical Medical Centre

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Charity

Funder Name

Princess Beatrix Funds (Prinses Beatrix Fonds) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration