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

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/09/2008	Musculoskeletal Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR169

Study information

Scientific Title

Study objectives
Dexamethasone pulse therapy is saver 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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Myositis, dermatomyositis, polymyositis

Interventions
1. 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.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Dexamethasone, prednisone

Primary outcome measure
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

Secondary outcome measures
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. Neuromusclular symptom score

Overall study start date
01/07/2001

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

Age group
Not Specified

Sex
Both

Target number of participants
80

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)

Sponsor details
Meibergdreef 9
Amsterdam
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1105 AZ

Sponsor type
University/education

Website
http://www.amc.uva.nl/

ROR

https://ror.org/03t4gr691

Funder(s)

Funder type
Charity

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration