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Prednisolone versus dexamethasone in chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) trial

Submission date 14/07/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/09/2005	**Overall study status** Completed	
Last Edited 07/01/2021	**Condition category** Nervous System Diseases	

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
MEC02/007 PREDICT

Study information

Scientific Title
Prednisolone versus dexamethasone in chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) trial

Acronym
PREDICT

Study objectives
Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) is an immune-mediated disorder. CIDP is characterised by motor and/or sensory symptoms and signs in more than one limb, developing over at least two months. The disease runs a progressive, relapsing-remitting or monophasic course. Loss of reflexes is found in almost all patients, but may be confined to the ankles. The diagnosis of CIDP is based on the clinical, electrophysiological, cerebrospinal fluid features and, to a limited degree, on histopathology. Cerebrospinal fluid protein levels are generally elevated without cellular reaction.

Primary objective:
Induces pulsed high dose dexamethasone treatment remissions more often than standard prednisolone treatment in patients with CIDP?
Secondary objectives:
1. Induces pulsed high dose dexamethasone treatment remissions more rapidly than standard prednisolone treatment?
2. Is pulsed high dose dexamethasone treatment more effective than standard prednisolone treatment in improving disability and impairment?
3. Has pulsed high dose dexamethasone treatment less side effects than standard prednisolone treatment?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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

Chronic inflammatory demyelinating polyradiculoneuropathy

Interventions
1. Experimental treatment:
After randomisation a patient will start with 6 cycles of dexamethasone 40 mg per day orally for 4 consecutive days, repeated every 28 days. The cycles start in week 1, 5, 9, 13, 17, and 21. Simultaneously, patients will be treated with placebo according to the regimen described under alternative treatment.
2. Alternative treatment: After randomisation a patient will start with prednisolone 60 mg per day for 4 weeks. Subsequently, prednisolone will be tapered to alternate day dose and further decreased over time. Total treatment length will be 32 weeks. Simultaneously, patients will be treated with placebo according to the regimen described under Experimental treatment.
Patients in the experimental and alternative treatment group receive equivalent cumulative doses of corticosteroids during the study.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Prednisolone, dexamethasone

Primary outcome measure
The primary outcome measure has been defined as the proportion of patients in remission at 12 months after start of first treatment. A remission is defined as improvement of at least 3 points on the Rivermead mobility index ánd an improvement of at least 1 point on the INCAT disability scale as compared with baseline. Each relapse during the follow-up period will be considered a treatment failure and excludes the possibility of a remission at 12 months.

Secondary outcome measures
1. Time to reach remission
2. Proportion of patients with relapse at 12 months
3. Time to relapse
4. Proportion of patients with at least 3 points improvement on the Rivermead mobility index
5. Proportion of patients with at least 1 point improvement on the INCAT disability scale
6. Mean differences in grip strength as assessed with a handheld Vigorimeter in kg between dexamethasone and prednisolone treated group
7. Mean differences in MRC sum score between dexamethasone and prednisolone treated group
8. Changes in INCAT sensory sum score between dexamethasone and prednisolone treated group
9. Mean differences in SF-36 quality of life score between dexamethasone and prednisolone treated group
10. Electrophysiological parameters
11. Weight, blood pressure
12. Laboratory values
13. Bone densitometry of the lower spinal vertebra and a visit to an ophthalmologist to exclude glaucoma and cataract (within first 4 weeks after inclusion)
14. Side effects

Overall study start date
01/07/2002

Completion date
01/01/2009

Eligibility

Key inclusion criteria
Eligible patients have to have signs and symptoms consistent with CIDP according to the diagnostic criteria as defined by a Dutch Consensus group in 1997. These criteria are derived from the much used and cited criteria of the ad hoc subcommittee of the American Academy of Neurology AIDS Task Force 1991 but contain a few practical modifications. Only definite or probable CIDP patients will be included.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
52

Total final enrolment
40

Key exclusion criteria
1. Abnormal erythrocyte sedimentation rate, hemoglobulin, white cell count, immuno-electrophoresis or immunofixation (with the exception of an IgG MGUS), TSH, Vitamin B1/B12, gamma-GT, or glucose
2. Pleocytosis in cerebrospinal fluid (CSF) of more than 90/3 (30/mm^3)
3. Received treatment for CIDP before
4. Use of drugs which are known to cause neuropathy
5. Age under 18 years
6. Contraindication for corticosteroid treatment
7. Pregnancy or active wish to become pregnant
8. Diseases known to cause neuropathy or to reduce mobility
9. Diseases known to lead to severe handicap or death at short notice
10. Patients with a subacute inflammatory demyelinating polyneuropathy (SIDP); this is a subset of patients with spontaneous recovery within 3 months and a monophasic course
11. Pure motor CIDP: no sensory signs or symptoms and no abnormalities in sensory nerve conduction studies (SNAP, SNCV, SDLT)
12. Refusal to give informed consent or withdrawal of previously given permission

Date of first enrolment
01/07/2002

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Meibergdreef 9
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Sponsor type
University/education

Website
http://www-amrweb/website/Home.htm

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Charity

Funder Name
Prinses Beatrix Fonds (charity-trust); Trialnumber MAR01-0213.

Funder Name
Dept of Neurology, Academic Medical Center.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2010	07/01/2021	Yes	No