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

**Submission date**
14/07/2005

**Recruitment status**
No longer recruiting

**Registration date**
07/09/2005

**Overall study status**
Completed

**Last Edited**
07/01/2021

**Condition category**
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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**Contact details**
Meibergdreef 9
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## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
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.

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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**
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# Sponsor information

**Organisation**
Academic Medical Centre (AMC) (The Netherlands)

**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

## 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 |