

Patients with chronic idiopathic axonal polyneuropathy: relationships in the disablement process

Submission date 29/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/06/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/03/2008	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr N.L.U. van Meeteren

Contact details

University Medical Center Utrecht
Department of Neurology and Neurosurgery
Rudolf Magnus Institute of Neuroscience
P.O. Box 85500
Utrecht
Netherlands
3508 GA
n.vanmeeteren@umcutrecht.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2006-01

Study information

Scientific Title

Acronym

EXAMPLE part II

Study objectives

1. A specific set of variables of impairments are related or predictive of functional limitations and disabilities
2. A specific set of variables of functional limitations are related or predictive of disabilities
3. Psychological variables (defined by theory of planned behaviour [TPB], anxiety and depression) add to impairment variables in the prediction of functional limitation (in self-report and performance measures)
4. These psychological variables mediate the relationship between impairment and functional limitations

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Longitudinal study; one patient group with CIAP in which the health status will be monitored

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Chronic idiopathic axonal polyneuropathy (CIAP)

Interventions

None: this is a longitudinal study with one patient group with chronic idiopathic axonal polyneuropathy (CIAP), in which the health status will be monitored

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Parameters of four domains of the disablement process will be measured:

1. Impairment: muscle strength (hand-held dynamometry), balance (Berg balance scale), sensory function (sensory modality score), pain (McGill pain questionnaire), fatigue (fatigue severity scale)
2. Functional limitations: walking (modified shuttle walk test), physical functioning (physical functioning performance 10 test), hand functioning (button test and disabilities of the arm, shoulder, and hand questionnaire), physical activity (DigiWalker stepcounter), problematic activities (McMaster-Toronto arthritis patient function preference questionnaire)
3. Disability: autonomy and participation (impact on participation and autonomy questionnaire and Rankin score)
4. Intra-individual risk factor: cognitions; intentions and perceptions of control (TPB questionnaire), emotions (hospital anxiety and depression scale)

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/03/2006

Completion date

01/03/2008

Eligibility**Key inclusion criteria**

1. Patients with chronic idiopathic axonal polyneuropathy (CIAP), diagnosed on established criteria
2. Patients who write and speak the Dutch language well
3. Signed informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

90

Key exclusion criteria

1. Relevant co-morbidity, expected to influence the test results
2. Anticipated health risks during performance-based testing

Date of first enrolment

01/03/2006

Date of final enrolment

01/03/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Utrecht

Utrecht

Netherlands

3508 GA

Sponsor information

Organisation

University Medical Center Utrecht (UMCU) (The Netherlands)

Sponsor details

Department of Rehabilitation

P.O. Box 85500

Utrecht

Netherlands

3508 CA

Sponsor type

University/education

ROR

<https://ror.org/0575yy874>

Funder(s)

Funder type

University/education

Funder Name

University Medical Center Utrecht (UMCU) (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