Rehabilitation of functional muscle and motor capacity in neurodegenerative disease: Multiple Sclerosis research

Submission date	Recruitment status	Prospectively registered
19/08/2009	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
01/10/2009	Completed	Results
Last Edited	Condition category	Individual participant data
01/10/2009	Nervous System Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 050078 IWT TETRA

Study information

Scientific Title

Rehabilitation of functional muscle and motor capacity in neurodegenerative disease: a single centre placebo-controlled Multiple Sclerosis research trial

Acronym

MS rehabilitation

Study objectives

Regular and moderately intense rehabilitation of muscle strength improves functional capacity in multiple sclerosis (MS) patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Board of Hasselt University approved on the 24th October 2005 (ref: CME 2005/233)

Study design

Single centre placebo-controlled clinical research trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Multiple sclerosis

Interventions

Patients will be subjected to different rehabilitation modes during a period of 24 weeks and according to a specific treatment protocol:

- 1. Control
- 2. Strength training
- 3. Strength training and electro-stimulation
- 4. Whole body vibration
- 5. Micro-electrotherapy

At baseline and following 12 and 24 weeks of therapy all endpoints will be measured.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Measured at baseline, mid- (after 10 weeks intervention) and post-treatment (after 20 weeks of intervention):

- 1. Maximal isometric muscle strength of knee-extensors and flexors
- 2. Isotonic and isokinetic dynamic muscle strength using an isokinetic dynamometer
- 3. Functional performances
- 4. Blood samples
- 5. Motor control (surface electromyography [sEMG], in-phase and anti-phase motor coordination test equipment)
- 6. Quality of life (specific questionnaire) assessment

Secondary outcome measures

- 1. Visual Analogue Scale (VAS) measured before and after each training session
- 2. Borg Scale measured after each training session

Overall study start date

01/11/2005

Completion date

01/12/2007

Eligibility

Key inclusion criteria

- 1. MS patients (Expanded Standard Disbility Status Scale [EDSS] 0.5 3) that have functional muscle and motor functional disabilities
- 2. Males and females aged 20 65 years
- 3. 24-week availability

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

48 patients subjected to four different rehabilitation modes

Key exclusion criteria

- 1. Any pathology that is a contra-indication for rehabilitation training
- 2. Wheelchair dependency
- 3. No present physiotherapy (preferably)

Date of first enrolment

01/11/2005

Date of final enrolment

01/12/2007

Locations

Countries of recruitment

Belgium

Study participating centre

Guffenslaan 39

Hasselt Belgium B-3500

Sponsor information

Organisation

IWT Vlaanderen (Instituut voor de aanmoediging van Innovatie door Wetenschap en Technologie in Vlaanderen) (Belgium)

Sponsor details

Bischoffsheimlaan 25 Brussel Belgium B-1000

Sponsor type

Research organisation

Website

http://www.iwt.be/

ROR

https://ror.org/032xdry56

Funder(s)

Funder type

Research organisation

Funder Name

IWT Vlaanderen (Instituut voor de aanmoediging van Innovatie door Wetenschap en Technologie in Vlaanderen) (Belgium) (ref: 050078)

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration