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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

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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 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