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Effectiveness of robotic-assisted walking (lokomat) on quality of life, gait, activity level, and balance in patients with multiple sclerosis

Submission date
02/04/2007

Recruitment status
No longer recruiting

Registration date
10/09/2007

Overall study status
Completed

Last Edited
12/11/2013

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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Montana07

Study information

Scientific Title

Acronym
Montana

Study objectives
1. To test the hypothesis that an automated (robotic assisted) locomotor training with the Lokomat in addition to a standard rehabilitation programme is more efficacious than a walking training in addition to a standard rehabilitation in influencing the short and long-term outcome (walking distance in three minutes, health related quality of life, and gait quality) of patients with multiple sclerosis with an Expanded Disability Status Scale (EDSS) 3 to 7.0
2. To investigate whether the activity level after the rehabilitation is different in the group with the automated locomotor training compared to the control group
3. To investigate whether the activity level during the inpatient rehabilitation is different compared to the level before the rehabilitation period
4. To investigate whether the immediate, short time influence on gait parameters (symmetry and frequency) are different in the two treatment groups

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Ethic Commission Canton Valais (Switzerland) on the 20th February 2007 (ref: CCVEM 008/07).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions

All interventions will take place in a rehabilitation setting (three weeks). All interventions during the rehabilitation period (three weeks) are based on scientific evidence, on expert consensus and on patient preferences.

Control (traditional):
Gait-training in group three times a week, maximum of 30 minutes walking, individual physiotherapy including balance related training, three times per week, MOTOmed, hippotherapy, 'neuro'-group in water, sitting group/mat group, no treadmill training.

Intervention (Lokomat):
Automated locomotor training three times a week, maximal of 30 minutes of walking, individual physiotherapy including balance related training, three times per week, MOTOmed, hippotherapy, 'neuro'-group in water, sitting group/mat group, no treadmill training.

Although the rehabilitation is defined 'traditional' rehabilitation it is based on newest evidence and on patient preference. The volume (intensity and frequency) of the interventions are defined by the patients and the medical team.

Intensity of training is defined by the patients its self-evaluation, the patient should work with an intensity of 13 to 17 on the Borg scale (6 to 20) (Borg Dyspnea Scale, which has shown a good mean to monitor and regulate physical exercise). To prevent persistent deterioration of the patient's condition, the level of exertion and well being is evaluated two hours after every training session and intensity will be adapted in the next training sessions if fatigue, exertion and well-being is reduced.

Physiotherapy will be administered and directed in accordance with the ideas, experience and techniques of the personal physiotherapist. This might typically include body awareness training, posture and dynamic control, and non-impact aerobic exercises, accompanied by a range of passive modalities such as massage, stretching, electrotherapy, etc. No attempt will be made to standardise the therapy given by individual therapists, as the treatment is intended to address individual needs of the patients, in all their variety.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Quality of life will be measured at baseline, at discharge (three weeks) and at 3 and 12 months
2. Activity level will be measured during seven days before the rehabilitation, in the middle week of the rehabilitation, and 3 and 12 months after discharge of rehabilitation
3. Gait-parameters (symmetry, gait security, gait speed, gait capacity) will be measured only during rehabilitation setting (at baseline, before and after the third, sixth and ninth gait intervention)

Secondary outcome measures
1. Pain will be measured at baseline, before and after gait interventions (each time), each day in the evening, at three weeks (discharge rehabilitation), 3 and 12 months post rehabilitation

2. Fatique will be measured at baseline, before and after gait interventions (each time), each day in the evening, at three weeks (discharge rehabilitation), 3 and 12 months post rehabilitation
3. Spasticity will be measured at baseline and discharge (at the end of three weeks rehabilitation)

Overall study start date
10/04/2007

Completion date
01/09/2010

Eligibility

Key inclusion criteria
1. Aged 18 or older
2. Diagnosed with multiple sclerosis confirmed by a specialist in neurology by the mean of the McDonald criteria
3. EDSS score equal or higher than 3 and lower or equal than 7.0
4. Able to walk 14 metres (with or without assistive devices)
5. Willingness to comply with any programme to which randomly assigned

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Disorders preventing active rehabilitation (cardiovascular, respiratory, orthopaedic, psychiatric, or other medical conditions, including unhealed decubitus and orthostatic hypotension; pregnancy)
2. Rehabilitation period planned of less than three weeks
3. One or more exacerbations in the preceding three months
4. More than 135 kg
5. Strong asymmetry of musculoskeletal system
6. Length of femur less than 34 cm

Date of first enrolment
10/04/2007

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
Switzerland

Study participating centre
Berner Klinik Montana
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
http://www.bernerklinik.ch/

Funder(s)

Funder type
University/education

Funder Name
Resar University of Applied Sciences in Western Switzerland (Switzerland) (Refs: ReSaR:10/O/06; HES-SO: ReSaR 09-06)

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	01/03/2012		Yes	No
Results article	results	09/07/2013		Yes	No