Gait adaptability assessment on the C-Mill in polio survivors.

Published: 25-08-2016 Last updated: 16-04-2024

Primary Objective: 1) To compare gait adaptability findings as assessed on an instrumented treadmill with projected obstacles and stepping targets (C-Mill) in polio survivors with those of healthy controls. Secondary Objectives:2) To determine the...

| Ethical review | Approved WMO |
|-----------------------|----------------------------|
| Status | Recruitment stopped |
| Health condition type | Neuromuscular disorders |
| Study type | Observational non invasive |

Summary

ID

NL-OMON47628

Source ToetsingOnline

Brief title Gait adaptability in polio survivors.

Condition

• Neuromuscular disorders

Synonym poliomyelitis; polio

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: C-Mill, Gait adaptability, Gait stability, Polio

Outcome measures

Primary outcome

The main outcome for this study is gait adaptability. Measures of gait adaptability that will be evaluated are:

1) Anticipatory and reactive obstacle avoidance performance (%), quantified as the percentage of successfully avoided obstacles during obstacle crossing while walking on the C-Mill.

2) Stepping accuracy of walking on regular or irregular patterns of stepping targets (mm), quantified in terms of the variation in foot placement relative to the stepping targets while walking on the C-Mill.

3) Gait stability during obstacle crossing and visually guided stepping,

quantified in terms of the medio-lateral and backward margins of stability (MoS).

Secondary outcome

Secondary study outcomes include: step length, step width, and step frequency during obstacle crossing and visually guide stepping; and balance skills (Timed up and go test and Berg Balance Scale), balance confidence (Activities specific Balance Confidence scale), fear of falling (Falls Efficacy Scale), and fall rate (falls questionnaire).

Study description

Background summary

Accidental falls are a major problem for aging polio survivors, especially for those suffering from post-polio syndrome. Because most falls in polio result from a trip, a slip, or a misplaced step while walking, gait adaptability is likely to be an important determinant of the risk of falls. Gait adaptability is defined as the ability to adapt one*s gait to environmental circumstances, such as obstacles, stepping targets and cluttered terrains. This multidimensional nature of gait adaptability may be a key reason why it is so difficult to measure in clinical practice. Most tests aimed at capturing aspects of gait adaptability, guantify overall success and time taken, rather than how the adaptations are achieved. Insight in how gait adaptations are achieved is needed to help develop rehabilitation interventions that aim to improve gait adaptability in polio survivors, which, in turn, may reduce the risk of falling. In addition, insight into the course of gait adaptability is important for the development of fall programs in these patients. In this study, we aim to assess the feasibility of an instrumented treadmill with projected visual obstacles and stepping targets (C-Mill) as a tool to provide quantitative in-depth information on gait adaptability and its course over time in polio survivors.

Study objective

Primary Objective:

1) To compare gait adaptability findings as assessed on an instrumented treadmill with projected obstacles and stepping targets (C-Mill) in polio survivors with those of healthy controls.

Secondary Objectives:

2) To determine the relation between gait adaptability findings with clinical measures of balance in polio survivors.

3) To assess changes in gait adaptability over a follow up period of two years in polio survivors.

4) To investigate the reproducibility of C-Mill gait adaptability assessment in polio survivors.

Study design

Prospective cohort study with four measurements in two years. Measurements will be performed at baseline (T1), and after 2 weeks (T2), 12 months (T3) and 24 months (T4). Measurements in healthy controls will only be performed at T1.

Study burden and risks

At study entry, patients will undergo a gait adaptability assessment, muscle strength assessment, balance testing and fall rate assessment. This will take

approximately 2 hours in total. Healthy subjects will only undergo an assessment of gait adaptability. At 12 and 24 months follow up, patients will be reassessed for gait adaptability, muscle strength, balance skills, and fall rate (2 hours per visit).

Risks for subjects undergoing the gait adaptability assessment are minimal. While there are no direct benefits to the participants, the findings can be used to more accurately obtain information on gait adaptability and the course of gait adaptability in aging polio survivors. This can guide fall interventions programmes aimed at reducing (accidental) falls in polio and encourage further research into new evidence based treatment in this area.

Contacts

Public Academisch Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Patients: -confirmed history of paralytic poliomyelitis; -age between 18 and 80 years; -at least walking indoors without walking aids; -at least one fall reported in the past year., Control subjects: -age between 18 and 80 years.

Exclusion criteria

Patients and control subjects:

-other pathologies/co-morbidities directly associated with increased fall risk such as: vestibular pathology, peripheral neuropathy and Parkinson's Disease.

Study design

Design

| Study type: | Observational non invasive |
|---------------------|---------------------------------|
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

Recruitment

| NL | |
|---------------------------|---------------------|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 14-12-2016 |
| Enrollment: | 75 |
| Туре: | Actual |

Ethics review

| Approved WMO | |
|--------------------|--------------------|
| Date: | 25-08-2016 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO | |
| Date: | 28-02-2019 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO | |
| Date: | 05-03-2020 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| | |

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register CCMO

ID NL57445.018.16