Postural responses to balance perturbations in individuals with Supratentorial Stroke and Idiopathic Parkinson's Disease

Published: 07-04-2011
Last updated: 28-04-2024

In PD patients: To investigate the effect of Levodopa on postural responses after translational perturbations. These outcomes will be helpful to decide whether patients in the cohort study should be measured in the ON or OFF medication state. In...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neurological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON36220

Source
ToetsingOnline

Brief title
Posture Stroke PD

Condition

- Neurological disorders NEC

Synonym
Parkinson's Disease, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Nijmegen Centre For Evidence Based Practice (NCEBP)

Intervention

Keyword: Parkinson's Disease, Postural responses, Stroke

Outcome measures

Primary outcome

The stepping threshold, defined as the highest perturbation intensity (in m/s2)

at which balance is maintained with a feet in place response.

Secondary outcome

- Kinematic variables such as joint angles and Centre of Mass (CoM)

- Margin of Stability defined as the minimum distance between the vertical

projection of the CoM and the border of the Base of Support (BoS) during

perturbations at the stepping threshold.

- EMG (electromyographic) variables such as onset latency and amplitude.

Study description

Background summary

Falls are a major health problem in our aging population. Since balance deficits are the most important risk factor for falls, it is not surprising that in the population of Parkinson (PD) and stroke patients, in whom balance deficits are very common, the problem of falls is paramount. We have planned a prospective cohort study using a new experimental setup (Radboud Falls Simulator) where we intend to predict falls and to better understand the mechanisms of postural instability in PD and stroke patients. For both groups, some questions remain to be answered to improve the interpretation of the results of cohort study. These separate questions will be addressed in two pilot studies as described in the current proposal.

Study objective

In PD patients: To investigate the effect of Levodopa on postural responses after translational perturbations. These outcomes will be helpful to decide whether patients in the cohort study should be measured in the ON or OFF medication state. In addition, the results will provide more information about the role of the dopaminergic system in postural stability in PD patients.
In stroke patients: To determine the effect of Weight Bearing Asymmetry (WBA) on postural stability. Since WBA is common in stroke patients, the outcomes are useful for the interpretation of the results of the cohort study. Furthermore, the reusults give more insight in the mechanisms of balance control in stroke patients.

Study design

Experimental study with repeated measurements.

Study burden and risks

Patients will have to visit the hospital for a balance assessment (1 visit for stroke AND 2 visits for PD). During the balance assessment participants will be exposed to balance perturbations by sudden translations of the support surface. The risks of participating in the balance assessment are very small, since rails are mounted around the balance platform and participants wear a safety harness. PD patients will be measured in their medication OFF state once, which means that they have to skip one dose of dopaminergic medication. This procedure is completely safe and internationally accepted. After the assessments, that will be planned in the morning, patients can take the missed medication dose and continue the regular medication schedule.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All participants:
- Functional Ambulation Categories 3-5
- Age 18 years and older
- Ability to stand independently (on bare feet) for at least 30 minutes
Stroke patients:
- Unilateral Supratentorial Stroke longer than 6 months ago
Parkinson patients:
- Idiopathic Parkinson's Disease
- Hoehn & Yahr Stages 1-3

Exclusion criteria

- Any other neurological or musculoskeletal disorder affecting balance
- Any inability to cooperate with the assessments and to give written informed consent
- Medication negatively affecting balance (e.g. neuroleptics, antidepressants, anticonvulsants, sedatives).

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2011
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	07-04-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	ID
CCMO	NL35969.091.11