Objective qualification of balance control and arm function in stroke subjects using on-body sensing - evaluation of principles in a simulated ambulatory setting

Published: 06-02-2013
Last updated: 19-03-2025

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40017

Source
ToetsingOnline

Brief title
Objective qualification of motor function, in stroke subjects

Condition

- Central nervous system vascular disorders

Synonym
cerebrovascular accident, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: ambulatory, monitoring, qualification, stroke

Outcome measures

Primary outcome

Main study parameters are correlation values between the selected parameters to assess balance and reaching performance using body-mounted sensors and the results of frequently used clinical assessments of balance and motor function.

Secondary outcome

The temporal and kinematic parameters (for example: timing, movement distance and number of steps) estimated with the experimental movement analysis systems and reference measurements are secondary parameters.

Study description

Background summary

With the aging of the population, the incidence of stroke is increasing in especially western countries. Depending on the patient*s impairments as a result of the stroke, a patient-specific rehabilitation program is started when he/she is discharged from the hospital after the acute phase. During the subsequent period of intensive training in a rehabilitation centre, the patient*s motor function is regularly evaluated. When the patient has an adequate capacity to live at home, the patient is discharged and sent home. Between this moment and the next routine appointment (several months later), patients frequently show deterioration of motor function. In some cases, this deterioration is so severe that re-admission to a rehabilitation centre is necessary. Remarkably, the cause of the deterioration of motor function is unknown in many cases, since the patient*s period at home is like a black-box for the physician. If the physician would be able to monitor the patient*s

motor function at home, he could intervene in case of deterioration and prevent an expensive re-hospitalisation. For this purpose, we develop body-mounted sensing systems that can eventually result in daily-life monitoring. In the current phase, we evaluate monitoring principles in a simulated ambulatory setting. In this cross sectional study described in this document, a combination of two ambulatory human movement analysis systems (Instrumented Force Shoes and an inertial sensing suit) will be used to assess balance and reaching tasks of stroke patients. The results will be evaluated and related to regular clinical tests.

Study objective

The primary objective is to investigate which balance and reaching performance measures - estimated using body-mounted sensing - correlate with frequently used clinical assessments of balance and motor function, while measuring stroke patients in a simulated ambulatory setting. A secondary objective is to demonstrate the correspondence between temporal and kinematic parameters (for example: timing, movement distance and number of steps) estimated with the experimental movement analysis systems and reference measurements.

Study design

Cross sectional design, one measurement session in one group of stroke patients.

Study burden and risks

There is no risk associated with participating in the measurements. There will be only one measurement session. This measurement session will take about 120 minutes, of which 60 minutes are preparation time. During all measurements, subjects can take rest at any moment they like, to prevent fatigue. Two researchers will accompany the subjects during all measurements. There is no direct benefit for the patient by joining the measurements

Contacts

Public
Universiteit Twente

Drienerlolaan 5
Enschede 7522 NB
NL
Scientific
Universiteit Twente

Drienerlolaan 5
Enschede 7522 NB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

At least 6 months post-stroke. Age between 35 and 75. The patient had only one ischaemic or haemorrhagic hemiparetic stroke.

Exclusion criteria

Medical history of more than one stroke events.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-05-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	06-02-2013
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	24-10-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23377
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL41791.044.12
Other	NTR (TC=3636)
OMON	NL-OMON23377