Can the predefined on-body sensing system be used for the qualification of the arm and balance function of patients after stroke.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23377

Source
NTR

Health condition

Stroke Beroerte

Sponsors and support

Primary sponsor: Primary sponsor - This project is part of the Seventh Framework Programme (FP7) funded by the European Union.
Source(s) of monetary or material Support: Primary sponsor - This project is part of the Seventh Framework Programme (FP7) funded by the European Union.

Intervention

Outcome measures

Primary outcome

Using on-body sensing systems, inertial sensors, force sensors and EMG-sensors; movement, forces and muscle activity will be measured. Measured data will be analyzed and the main

study parameters will be calculated. These parameters are subdivided into three groups: temporal (number of movements), kinetic (centre of pressure, underneath the foot) and kinematic (step width, step size, range of motion). Each group contains several parameters of which a combination of parameters and/or (a)symmetry of parameters will be used to qualify motor function.

Secondary outcome

Secondary parameters are the clinical tests (Timed Up and Go Test, Berg Balance Scale, Fugl Meyer, Stroke Upper Limb Capacity Scale, Barthel index) which are already used in clinical practice to assess balance, reaching tasks and daily-life activity. The results of these tests will be correlated to the results of primary study parameters by calculating the regression coefficients and intraclass correlation between the clinical tests and the parameters as described in the main parameters.

Study description

Background summary

With the aging of the population, the incidence of stroke is increasing in especially developing 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.

Recruitment only in the Netherlands.

Study objective

The predefined on-body sensing system can be used for the qualification of the arm and balance function of patients after stroke.

Study design

One moment.

Intervention

For all subjects the experiment will be the same. No randomization will be aplied, no control group will be included.

During the single measurement session, the sensors will be attached to the body. After calibration, subjects will be asked to perform some specific tasks and complete some clinical tests. The whole measurement session will take about 120 minutes.

Contacts

Public
University of Twente
Biomedical Signals and Systems
Zuid-Horst ZH 229
P.O. 217
F.B. Meulen, van
Enschede 7500 AE
The Netherlands
+31 (0)53 4892740
Scientific
University of Twente
Biomedical Signals and Systems
Zuid-Horst ZH 229
P.O. 217
F.B. Meulen, van
Enschede 7500 AE
The Netherlands
+31 (0)53 4892740

Eligibility criteria

Inclusion criteria

1. Age above 35 years;

2. Age below 75 years;

3. At least 6 months post-stroke;

4. Had only one unilateral ischaemic or haemorrhagic hemiparetic stroke;

5. Ability to lift the arm (at least partly) against gravity, without suffering;

6. Ability to walk (possibly with walking aid) for over 10 meters, without suffering;

7. Ability to walk without specific footwear (ability to walk on sandals);

8. No pain or other condition interfering with the mobility and/or strength of the arm;

9. Ability to understand and perform instructions and questionnaires;

10. Provide written informed consent (IC).

Exclusion criteria

1. Medical history of more than one stroke events;

2. Complicating medical history such as cardiac, pulmonary, or orthopaedic disorders that could affect performance of the included measurements;

3. Severely impaired sensation;

4. Suffering from comprehensive aphasia.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2013
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 40017
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3490
NTR-old	NTR3636
CCMO	NL41791.044.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40017

Study results

Summary results
N/A