Recovery after stroke

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25904

Source
NTR

Brief title
PROFITS

Health condition

beroerte (CVA)/stroke, prognose/prognosis

Sponsors and support

Primary sponsor: Erasmus MC Rotterdam, VU University Medical Center Amsterdam
Source(s) of monetary or material Support: ZON-MW

Intervention

Outcome measures

Primary outcome

Brunnstrom Fugl-Meyer Assessment (arm and leg section), ARAT score, and 10 meter walk test at week 12 and 26.

Secondary outcome

- Demographics and phenotype of patients

- Premorbid functioning

- Neurological status (National Institute of Health Stroke Scale, Motricity Index, O-letter Cancellation Test, Montreal Cognitive Assessment, Erasmus MC Modification of the (revised) Nottingham Sensory Assessment, Standardized Swallowing Assessment, Aphasia Bedside Check, Frenchay Arm Test, Trunk Control Test, Timed Balance Test)

- Activities and participation (Barthel Index, Functional Ambulatory Categories, modified Rankin Scale, Berg Balance Scale, number of falls)

- Self-reported (Nottingham Extended Activities of Daily Living, Motor Activity Log, Stroke Impact Scale, Fatigue Severity Scale, Hospital Anxiety and Depression Scale)

- Physical behaviour (accelerometry-based ambulatory monitoring)

- EEG

Study description

Background summary

Functional recovery at 6 months post stroke appears to be largely defined within the first 72 hours after stroke onset. In addition, most of the time dependent dynamic changes in recovery plateau within 8-12 weeks after stroke onset. The majority of patients show a fixed proportional change of about 70% of their initial baseline level. However, 30% of patients with an initial poor prognosis are identified improperly. Therefore, prediction models of functional outcome post stroke need further improvement. Moreover, prediction rules need to be verified in those patients that were excluded from above-mentioned longitudinal studies due to co-morbidity, repetitive strokes and/or hemorrhagic strokes. These prediction rules should be able to handle the large variety in stroke patients that is currently encountered in our stroke units. Answering aforementioned questions requires uniform, repeated and time-fixed assessment of determinants and measures of functional outcome after stroke. Additional neurophysiological assessment may be needed to improve prognostic models.

Study design

Clinical assessments are repeated at week 1, 3, 5, 8, 12, and 26. The accelerometry-based ambulatory monitoring measurements are performed in week 3, 12, and 26. The EEG measurements are performed in week 1, 5, 8, and 12.

Intervention

Not applicable, all subjects will receive usual rehabilitation care independently from each other and from the researchers according to prevailing guidelines.

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Eligibility criteria

Inclusion criteria

(1) ischemic or hemorrhagic stroke; (2) upper limb paresis as defined by NIHSS motor arm item 0

Exclusion criteria

(1) more than 3 weeks post stroke; (2) pacemaker or other metallic implants for a subset of subjects (which will participate in the EEG protocol)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-09-2016
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-03-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44838
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6351
NTR-old	NTR6535
CCMO	NL54449.078.15
OMON	NL-OMON44838

Study results