Recovery after stroke

Gepubliceerd: 30-03-2017 Laatst bijgewerkt: 19-03-2025

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25904

Bron
NTR

Verkorte titel
PROFITS

Aandoening

beroerte (CVA)/stroke, prognose/prognosis

Ondersteuning

Primaire sponsor: Erasmus MC Rotterdam, VU University Medical Center Amsterdam
Overige ondersteuning: ZON-MW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Postbus 23181
J. Slaman
Rijndam Rehabilitation

Rotterdam 3001 KD
The Netherlands
+31102412412

Wetenschappelijk

Postbus 23181
J. Slaman
Rijndam Rehabilitation

Rotterdam 3001 KD
The Netherlands
+31102412412

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

(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)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	09-09-2016
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-03-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44838
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten