Timing of providing ankle-foot orthoses in stroke rehabilitation.

Gepubliceerd: 27-07-2009 Laatst bijgewerkt: 13-12-2022

Early provision of AFOs (± 2 wks after stroke) is expected to positively affect walking impairments, mobility and activities of daily living after acute stroke compared to providing AFOs later on in the rehabilitation process (± 10 wks after stroke...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19992

Bron
NTR

Verkorte titel
N/A

Aandoening

stroke; ankle-foot orthoses; rehabilitation; walking impairments; mobility; ADL; falling; QoL. beroerte/CVA; enkel-voet orthesen; revalidatie; stoornissen in loopfunctie; mobiliteit; ADL; vallen; kwaliteit van leven.

Ondersteuning

Primaire sponsor: Roessingh Research & Development b.v. Enschede
Overige ondersteuning: Ministry of Health, Welfare and Sport

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Clinical tests:
1. 10m walking test;
2. 6min walking test;
3. Functional Ambulation Categories;
4. Timed Up&Go test;
5. Stairstest;
6. Rivermead Mobility Index;
7. Berg Balance Scale;
8. Barthel Index;
9. Nottingham extended ADL index.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:
Ankle-foot orthoses (AFOs) are often used in the rehabilitation after stroke. The effects of AFOs are mainly studied performing cross-over studies to assess the immediate and short-term effects. Evidence for long-term effects, and especially research studying the timing of providing AFOs is lacking. In order to study the effects of timing of providing AFOs after stroke a new longitudinal research is proposed. In this explorative study acute stroke patients will be included and 2 intervention groups will be arranged. Both intervention groups will differ in the moment in which the AFO will be provided during the rehabilitation process.
Objective:
To study the effects of timing of providing AFOs on mobility related activities and activities of daily living in acute stroke patients in a rehabilitation setting. Secondary, the effects of timing of providing AFOs on walking impairments, occurrence of falls and fall related events and the effect on quality of life is studied.
Study design:
Longitudinal design with randomisation for the intervention, parallel groups.
Study population:
Acute stroke patients admitted into the Roessingh Rehabilitation Centre in Enschede will participate. Subjects with an indication to use an AFO because of problems with stability in stance, problems with footclearance during swing or problems with foot prepositioning in early stance will be included.
Intervention:
Timing of providing AFOs will be compared in 2 groups:

1. Providing an AFO within one week after admission into the rehabilitation centre (approximately 2 weeks after stroke);

2. Providing an AFO 8 weeks later.
Main study parameters/endpoints:
Mobility related activities and activities of daily living (clinical tests, questionnaires).

Secondary study parameters are walking impairments (gait analysis, instrumented tests, clinical tests), occurrence of falls and fall related events and quality of life after stroke (questionnaires).

Doel van het onderzoek

Early provision of AFOs (± 2 wks after stroke) is expected to positively affect walking impairments, mobility and activities of daily living after acute stroke compared to providing AFOs later on in the rehabilitation process (± 10 wks after stroke). Furthermore, early provision of AFOs is expected to positively affect falling and quality of life.

Onderzoeksopzet

1. Gait analysis: in week 1, 9, 17, 26 and 52;

2. Clinical tests: during the first 18 weeks of the study: 2-week interval, and in week 26 and 52.

Onderzoeksproduct en/of interventie

Timing of providing an ankle-foot orthosis during the rehabilitation after stroke.

Early provision of AFOs (± 2 weeks after stroke) will be compared with providing an AFO 8 weeks later.

Contactpersonen

Publiek

Roessingh Research and Development | University of Twente
Corien Nikamp
Roessinghsbleekweg 33B

Enschede 7522 AH
The Netherlands
+31 (0)53 487 5762

Wetenschappelijk

Roessingh Research and Development | University of Twente
Corien Nikamp
Roessinghsbleekweg 33B

Enschede 7522 AH
The Netherlands
+31 (0)53 487 5762

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Admission into the Roessingh Rehabilitation Centre, Enschede;

2. Single and first ever unilateral ischaemic or haemorrhagic hemiparetic stroke;

3. Time since stroke max 3 weeks;

4. Age 18 years or older;

5. Indication to use an AFO during rehabilitation because of: problems with stability in stance; problems with footclearance during swing; problems with foot prepositioning in early stance;

6. No severe deficits in communication;

7. No severe deficits in memory and understanding.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Medical history of previous stroke(s);

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 severe neglect;

5. Suffering from comprehensive aphasia.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2009
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	27-07-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1820
NTR-old	NTR1930
CCMO	NL28347.044.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A