Testen van een zacht exoskelet tijdens looptaken uit het dagelijks leven; XoSoft Gamma-prototype testen

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The objective of this proof-of-concept study is to test the feasibility of the gamma-prototype of the lower limb exoskeleton XoSoft during locomotion-tasks related to daily life in stroke and incomplete spinal cord injury patients in a controlled...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20675

Bron
Nationaal Trial Register

Verkorte titel
XoSoft gamma-prototype testing

Aandoening

subjects with stroke and incomplete spinal cord injury

Ondersteuning

Primaire sponsor: Roessingh Research and Development performs the trial in collaboration with the other partners within the European H2020 XoSoft project. Project leader: J. Ortiz, Fondazione Istituto Italiano di Tecnologia, Genova, Italy
Overige ondersteuning: European Union, Horizon 2020 framework programme for research and innovation H2020-ICT-2015 grant agreement No 688175

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The feasibility of the system is tested by objective qualitative and quantitative evaluation of the gait pattern data, comparing the system in Active and InActive state with the locomotion pattern without wearing the system.

Kinematics (hip/knee/ankle angles, foot clearance, trunk kinematics) spatiotemporal (walking speed, duration of gait phases) and control-strategy parameters (amount, timing, duration, consistency of the actuation) are evaluated.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Various types of exoskeletons were developed in the last decade to assist people with mobility impairments. Most of the existing exoskeletons have a rigid structure, heavy weight and a bulky design, which limits the use during activities of daily living and in the home environment. Therefore, a new project called XoSoft was conducted, to develop a soft lower-limb exoskeleton to assist people with mobility problems. XoSoft aims for a flexible and lightweight structure requiring low power consumption.
Objective: 1) To test the feasibility of using the Gamma-prototype of lower-limb exoskeleton XoSoft during locomotion-tasks related to daily life in stroke and incomplete spinal cord injury (iSCI) patients; 2) To test the usability of the Gamma-prototype during locomotion-tasks related to daily life in stroke and iSCI patients.
Study design: A pilot study, planned as an open, randomized proof of concept study. All measurements are performed in a controlled environment. The subject’s normal locomotion pattern (without wearing the system) will be compared with the locomotion pattern while wearing the XoSoft system.
Study population: Maximal 10 medically stable subjects, at least 6 months after stroke or iSCI will be recruited. Subjects are ≥18 years of age and able to walk without physical help of another person (walking aids are allowed). Subject have problems during walking with respect to foot clearance in swing and/or stability in stance.
Intervention: First, the subjects locomotion pattern will be measured without wearing the system Inertial sensors will be used, while performing the 10m walking test, L-test and 8-figure walk test. Subsequently, Subjects will be measured while wearing the prototype and the system is activated (Active prototype) and while wearing the prototype and the system is in inactive state (InActive prototype). The order will be randomized. In the Active state the Gamma-prototype can provide support to the lower limb(s). The system can support a total of three joints (hip, knee and ankle) per side in both directions (flexion/extension), in any combination, depending on the needs of the subject. Subjects will perform locomotion-tasks related to daily life. This includes sit-to-stand/stand-to-sit, walking in straight line, turning and walking curves, tested using the 10m walking test, L-test and 8-figure walk test. Furthermore,

a daily-life task in a living-room like environment will be performed.
Main study parameters/endpoints: Kinematics (hip/knee/ankle angels, foot clearance, trunk kinematics), spatiotemporal (walking speed, duration of gait phases) and control-strategy parameters (amount, timing, duration, consistency of the actuation) are evaluated. Secondary, the usability of the system is tested by subjective evaluation of the opinion of participants that used the prototype. The System Usability Scale and a semi-structured interview will be used to gather information about users' experience.

Doel van het onderzoek

The objective of this proof-of-concept study is to test the feasibility of the gamma-prototype of the lower limb exoskeleton XoSoft during locomotion-tasks related to daily life in stroke and incomplete spinal cord injury patients in a controlled environment.

Onderzoeksopzet

3 visits are planned: one to fit and adapt the textile garment, 1 to attach all the hardware modules to the garment and 1 to perform measurements with the Active and InActive prototype

Onderzoeksproduct en/of interventie

Subjects will be measured while wearing the prototype and the system is activated (Active prototype) and while wearing the prototype and the system is in inactive state (InActive prototype). The order will be randomized. In the Active status the Gamma-prototype can provide support to the lower limb(s). The system can support a total of three joints (hip, knee and ankle) per side in both directions (flexion/extension), in any combination.

Subjects will perform locomotion-tasks related to daily life. This includes sit-to-stand/stand-to-sit, walking in straight line, turning and walking curves, tested using the 10m walking test, L-test and 8-figure walk test. Furthermore, a daily-life task in a living-room like environment will be performed.

In a previous visit the 10m walking test, L-test and 8-figure walk test will be performed without wearing the system. Wearable sensors will be used to measure the locomotion pattern without wearing the device.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-stroke or incomplete spinal cord, at least 6 months ago

-unilateral (for stroke) or uni- or bilateral (for iSCI) impaired

-able to walk without physical help of another person, walking aids are allowed (Functional Ambulation Categories score 3 or higher)

-age 18 years or older

-problems concerning walking with respect to foot clearance during swing and/or stability during stance phase

-able to read and understand questionnaires and able to execute commands

-able and willing to participate in the study

-signed inform consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Inability to wear the prototype due to health conditions (like wounds that can give a problem when wearing the system)

-in case ankle-foot orthoses are used in daily life: inability to walk without ankle-foot orthosis for 10m

-Severely impaired sensation of the lower limb

-Amputations or other musculoskeletal problems influencing locomotion

-Other neurological diseases or cardiopulmonary diseases influencing locomotion

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	28-08-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48537
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5053
NTR-old	NTR7450
CCMO	NL65466.044.18
OMON	NL-OMON48537

Resultaten