Trial Description

Title

Pilot study on feasibility and usability of the brain-computer interface-controlled MoreGrasp neuroprosthesis for individuals with cervical spinal cord injury

Trial Acronym

MoreGrasp

URL of the trial

http://www.moregrasp.eu

Brief Summary in Lay Language

The loss of the grasp function of both hands associated with a high spinal cord injury (SCI) severely limits the affected individuals' ability to live independently. Together with the fact that this type of injury often occurs in young people after sport or diving accidents, modern rehabilitation medicine aims at restoration of the grasp function to the highest possible degree. If not enough strong muscles are available for surgical improvement of the hand function neuroprosthesis based on the activation of muscles by electrical impulses applied with external electrodes on the skin (called Functional Electrical Stimulation (FES)) represent the only option for at least partial restoration of grasping.
The disadvantages of today's grasp neuroprostheses based on surface electrodes include large variations in finger movements depending on the wrist rotational position and the non-intuitive control of the hand opening/closing by movements of the contralateral shoulder measured by a joystick placed on the front of the shoulder.
To overcome these limitations, in the European project MoreGrasp (www.moregrasp.eu, grant no. H2020-643955) a novel FES-electrode array has been developed. This array consists of many small electrodes that can be electronically connected in a way that a stable grasp pattern is achieved independently of the wrist rotation. For control of this neuroprosthesis a novel, brain-computer interface using noninvasive wet electrodes on the skalp and based on the detection of imagined/attempted natural movement has been developed and evaluated in able-bodies subjects. This user interface, together with the shoulder joystick, might enable paralyzed end users to control the degree of hand opening/closing/rotation and selecting the desired grasp pattern in an intuitive manner. An additionally unique feature of the MoreGrasp system is its ability for personalization to the individual neurological and muscular status of the end users and their needs.
The aim of this multicenter study is the standardized and systematic assessment of the feasibility, usability and effectiveness of the noninvasive BCI-controlled MoreGrasp-neuroprosthesis in individuals with chronic (≥ 6 months since injury) high SCI and preserved shoulder function and elbow flexion, but restrictions in hand and finger function. As a perquisite for study participation the forearm muscles need to be sufficently activatable by external electrical, the wrist and finger passive joint mobility should not be limited and spasticity needs to be at a low level.

The study participation will be divided into three phases. First, the user takes part in a 4-12 week FES-training to increase fatigue resistance of the muscle groups relevant for grasping. BCI-training will be performed in parallel to the FES-training, during which 1) the computer learns to detect the general brain activation patterns associated to certain grasp patterns and 2) the user learns to improve this detection by playing an interactive video game. Subsequent to the training, an 8-week application phase follows during which the noninvasive neuroprosthesis will be used in a home setting. Finally, 8 weeks after end of the application phase a follow-up examination completes the study participation. During the study participation (approx. 7 months, dependent on the training duration) five examinations are performed every 8 weeks. During these visits, validated clinical assessments will be conducted. The duration of a single assessment visit will range between 1.5 and 4.5 hours depending on the number of tests and procedures applied per visit. Additionally, study participants will be contacted for status checks by phone at least every month.

Brief Summary in Scientific Language

The bilateral loss of the grasp function associated with a lesion of the cervical spinal cord severely limits the affected individuals' ability to live independently. Together with the fact that tetraplegia often occurs in young people after sport or diving accidents, modern rehabilitation medicine aims at restoration of the grasp function to the highest possible degree. If not enough strong muscles are available for surgical improvement of the hand function neuroprosthesis based on Functional Electrical Stimulation (FES) represent the only option for at least partial restoration of grasping.
The disadvantages of today's grasp neuroprostheses based on surface electrodes include large variations in finger movements depending on the wrist rotation angle and the non-intuitive control by preserved shoulder movements.
To overcome these limitations, in the European project MoreGrasp (www.moregrasp.eu, grant no. H2020-643955) a FES-electrode array has been developed together with external position and orientation sensors to automatically compensate electrodes shifts on the skin occurring during hand rotation and thereby achieving a stable grasp pattern. For control of this neuroprosthesis a novel, EEG-based brain-computer interface based on the detection of imagined/attempted natural movement has been developed and evaluated in able-bodies subjects. This user interface, together with a shoulder joystick, might enable paralyzed end users to control the degree of hand opening/closing/rotation and selecting the desired grasp pattern. An additionally unique feature of the MoreGrasp system is its ability for personalization to the neurological and muscular status of the end users and their needs.
The aim of this prospective, explorative, multicenter study is the standardized and systematic assessment of the feasibility, usability and effectiveness of the noninva-sive BCI-controlled MoreGrasp-neuroprosthesis in individuals with chronic (≥ 6 months since injury) high SCI and preserved shoulder function and elbow flexion, but restrictions in hand and finger function. As a perquisite for study participation the forearm muscles need to be innervated, the wrist and finger passive joint mobility should not be limited and spasticity needs to be at a low level.
The study participation will be divided into three phases. First, the user takes part in a 4-12 week FES-training to increase fatigue resistance of the muscle groups relevant for grasping. BCI-training will be performed in parallel to the FES-training, during which 1) the algorithms for detection of brain activation patterns will be tuned and 2) the user learns to improve the accuracy of the grasp pattern classification with an interactive video game. Subsequent to the training, an 8-week application phase follows during which the noninvasive neuroprosthesis will be used in a home setting. Finally, 8 weeks after end of the application phase a follow-up examination completes the study participation.

During the study participation (approx. 7 months, dependent on the training duration) five examinations are performed every 8 weeks. During these visits, validated clinical assessments based on the three domains of the International Classification of Functioning, Disability and Health (ICF) will be conducted. The duration of a single assessment visit will range between 1.5 and 4.5 hours depending on the number of tests and procedures applied per visit. Additionally, study participants will be contacted for status checks by phone at least every month.

Organizational Data

- DRKS-ID: **DRKS00013785**
- Date of Registration in DRKS: **2018/01/22**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **S-627/2017 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **G82.4 - Spastic tetraplegia**
- ICD10: **G82.3 - Flaccid tetraplegia**
- ICD10: **G82.5 - Tetraplegia, unspecified**

Interventions/Observational Groups

- Arm 1: **The study participation will be divided into three phases. First, the user takes part in a 4-12 week FES-training to increase fatigue resistance of the muscle groups relevant for grasping. BCI-training will be performed in parallel to the FES-training, during which 1) the algorithms for detection of brain activation patterns will be tuned and 2) the user learns to improve the accuracy of the grasp pattern classification with an interactive video game. Subsequent to the training, an 8-week application phase follows during which the noninvasive neuroprosthesis will be used in a home setting. Finally, 8 weeks after end of the application phase a follow-up examination completes the study participation.**
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depending on the number of tests and procedures applied per visit. Additionally, study participants will be contacted for status checks by phone at least every month.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Basic research/physiological study**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary outcome of the Pilot study is the general feasibility of the robust generation of different grasp patterns including lateral and palmar grasp with the MoreGrasp neuroprosthesis and their natural control by attempted/imagined movements detected by an EEG-based Brain-Computer Interface (BCI). This general feasibility will be assessed by the „Grasp-and-Release-Test“ with and without the neuroprosthesis

Secondary Outcome

1. Changes of body function in general during the 8 weeks of use of the active neuroprosthesis:
- active/passive range of motion (ROM) of upper limb joints
- neurological status assessed by the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI)
- Medical Research Council Scale (MRC) of upper extremities muscles
- spasticity assessed by the Modified Ashworth Scale (MAS)
- pain assessed by a numeric analogue scale
- depression assessed by Center for Epidemiological Studies Depressions-Scale (CES-D)
- relative and absolute grip force generated by FES

2. Changes in functional abilities during the 8 weeks of use of the active neuroprosthesis assessed by:
- Grasp-and-Release-Test (GRT)
- Van-Lieshout-Test Short Version (VLT-SV)
- Activities of daily living (ADLs)

3. Degree of satisfaction with the noninvasive neuroprosthesis assessed by:
- Assistive Technology Device Predisposition Assessment (ATD-PA, Section D)
- Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0)

4. Changes in quality of life over the course of the use of the active neuroprosthesis assessed by:
- Psychosocial Impact of Assistive Devices Scale (PIADS)
- Anamnestic Comparative Self-Assessment (ACSA)

Countries of recruitment

- DE **Germany**
- AT **Austria**

Locations of Recruitment

- University Medical Center **Klinik für Paraplegiologie, Heidelberg**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2018/02/01**
- Target Sample Size: **15**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Sub-acute to chronic cervical SCI with time since injury ≥ 6 months and missing or weak grasp function
- Age over 17
- Sufficient voluntary shoulder movements and elbow flexion on one side, preferably on the dominant side
- Capacity to consent

Exclusion criteria

- Severe restrictions in the passive range of movement of the joints of the upper limb (> 30% of physiological range of motion)
- Severe spasticity in the upper limbs
- Skin diseases like infections, psoriasis, burns etc. at the upper limbs
- Hyperesthesia of the upper limbs (upper and lower arm), which would not allow to increase FES intensity to a sufficient level of contraction force
- Cardiac pacemaker, other active implants like medication pumps, phrenic pacemaker etc.
- Metal implants in the direct area of current flow under the stimulation electrodes
- Plexus paresis or other injuries / diseases that lead to extensive denervation of muscles of the upper limbs
- Known history of epilepsy
- Severe cognitive impairment or psychiatric conditions that restrict the use of a neuroprosthesis
- Pregnancy

Addresses

■ **Primary Sponsor**

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Votum der Ethikkommission der Med. Fak. HD**
- Further trial documents **Web-basierte Studienregistrierung / web-based study registration**

** This entry means the parameter is not applicable or has not been set.*

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