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Active functional electrical stimulation

Submission date	Recruitment status	[_] Prospectively registered
08/01/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/01/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/02/2023	Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol

Background and study aims
Hand function is essential for daily living activities. People with spinal cord injury (SCI) can suffer from impaired hand functions. Conventional hand therapy is usually offered at the sub-acute stage of SCI but patients still experience significantly impaired hand function which affects their daily living activities and reduces their quality of life. A system has been developed that uses the electrical signal of the muscles to control functional electrical stimulation of the same muscles. The aim of this study is to determine the best parameters and confirm that people with SCI can adequately use the system both as a rehabilitative and assistive device.

Who can participate?
Patients aged 18–76 with high level SCI that affects their hand function

What does the study involve?
Each participant receives functional electrical stimulation to open and close the hand, controlled by the electrical signals of their muscles. There is a total of three sessions with each session lasting for a maximum of 2 hours.

What are the possible benefits and risks of participating?
There are no known direct benefits to participants but the result will help in further research in the area. There is no known risk as devices are certified.

Where is the study run from?
National Spinal Injuries Centre (NSIC), Stoke Mandeville Hospital, Buckinghamshire Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
Buckinghamshire Healthcare NHS Trust (UK)

Who is funding the study?
January 2017 to January 2019

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Active FES - v1

Study information

Scientific Title
Feasibility of two-channel proportional Electromyogram Controlled Functional Electrical Stimulation (EMG-FES) for augmentation of finger and wrist flexion and extension for application in active neurorehabilitation in spinal cord injury

Acronym
Active FES

Study objectives
There is evidence that active participation is important in movement rehabilitation. One of the methods of involving active participation during rehabilitation is to control rehabilitation system with voluntary effort. For this purpose, Electromyogram (EMG) has been investigated to trigger the onset or proportionally control the intensity of functional electrical stimulation (FES). The proportional control method is very attractive because it gives a more natural control but it is more difficult to implement because of the issues associated with recording EMG simultaneously with the application of FES. Recent developments have demonstrated potentials of single

channel proportional EMG controlled FES as an orthotic and rehabilitation system that can argument either tenodesis, hand flexion or extension. Here the aim is to further research and test the feasibility of a two-channel proportional EMG controlled FES system that can augment both hand and wrist flexion and extension in addition to tenodesis grasp and release

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Leeds East Research Ethics Committee, 06 /12/2017, REC ref: 17/YH /0416

Study design
Single-centre feasibility study of an interventional device

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Spinal cord Injury

Interventions
Each participant will receive functional electrical stimulation (FES) to open and close the hand. The FES will be controlled by the person's residual electromyogram. There will be a total of three sessions with each session lasting for a maximum of 2 hours.

Intervention Type
Device

Primary outcome measure
The following tests will be measured only once for each condition in the study:
1. Hand function, measured using Toronto rehabilitation institute hand function test (TRI-HFT)
2. Hand function, measured using trapezoidal shape tracing

Secondary outcome measures
The following tests will be measured only once for each condition in the study:
1. Physical well-being, assessed using the spinal cord independence measure (SCIM)
2. Spasticity muscle hypertonia levels, assessed using the Modified Ashworth Scale (MAS) test

3. Device usability and usefulness, assessed using a series of questionnaires including the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST)
4. Functional impairment, assessed using the International Neurological Standards for Spinal Cord Injury (ASIA impairment scale)

Overall study start date
04/01/2017

Completion date
30/08/2019

Eligibility

Key inclusion criteria
1. 18–76 years old
2. Sub-acute and chronic incomplete tetraplegia (neurological level C2 – T1), AIS grade B to D
3. Presence of residual EMG activity during hand flexion and extension

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15

Total final enrolment
15

Key exclusion criteria
1. Known neurological condition, comorbidity (e.g., brain injury)
2. A person unable to understand verbal or written information in English

Date of first enrolment
08/01/2018

Date of final enrolment
30/08/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Buckinghamshire Healthcare NHS Trust
Mandeville Road
Aylesbury
United Kingdom
HP21 8AL

Sponsor information

Organisation
Stoke Mandeville Hospital NHS Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0524j1g61

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Buckinghamshire NHS Trust Charitable Funds

Funder Name

Results and Publications

Publication and dissemination plan
Additional documents (such as study protocol, statistical analysis plan, other) are/will be available on request from Dr Bethel Osuagwu (bethel.osuagwu@gmail.com). Planned publication of the study results in a high-impact peer reviewed journal.

Intention to publish date
30/08/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/12/2020	27/02/2023	Yes	No
HRA research summary			28/06/2023	No	No