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Effects of cycling with afferent stimulation in subjects with spinal cord injury

Submission date
24/06/2016

Recruitment status
No longer recruiting

Registration date
15/07/2016

Overall study status
Completed

Last Edited
31/01/2018

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The spinal cord is a bundle of nerve fibres which is encased in a bony column (known as the spine). It is the most important link between the brain and the other nerves in the body (peripheral nervous system). Damage to the spinal cord (spinal cord injury, SCI) can lead to serious consequences. SCI can range from mild to severe, and can cause a partial or total loss of movement, often leaving people with life-long disability. Following SCI, patients usually undergo rehabilitation to improve functioning and quality of life. Normally, mobility is regulated by electrical impulses to and from the spinal cord. After SCI, this mechanism is disrupted, leading to mobility issues. Leg-cycling training is a commonly recommended exercise used in the rehabilitation of patients with SCI, as it requires similar signals between the legs and spinal cord. The aim of this study is to investigate the effects of combining cycling with electrical stimulation, in order to find out if the effects of the exercise can be enhanced.

Who can participate?
Adults with spinal cord injury and healthy non-injured adults

What does the study involve?
Participants with SCI an healthy participants are randomly allocated to undertake two tests spaced less than two weeks apart in a different order. One test involves 10 minutes of leg cycling alone, and the other involves 10 minutes of leg cycling with electrical stimulation. This is done by applying an electrical pulse a nerve through an electrode (sticky pad that conducts electricity) to the foot during the first minute of cycling. For patients with very severe SCI, they are helped with the cycling using a motor. Before and after each bout of cycling on the two days, participants have their reflexes measured through stimulating the nerves in the leg with electrical pulses.

What are the possible benefits and risks of participating?
There are no direct benefits or risks for participants taking part in this study.

Where is the study run from?
National Paraplegics Hospital of Toledo (Spain)

When is study starting and how long is it expected to run for?
January 2013 to June 2016

How long will the trial be recruiting participants for?
Ministry for Science and Innovation (Spain)

Who is the main contact?
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of sensorimotor neuro-rehabilitation strategies based on the application of electrical stimulation during the execution of rhythmical movements in subjects with spinal cord injury (SCI)

Acronym
NEUROTRAIN

Study objectives
1. Plantar cutaneous-conditioned spinal excitability would be depressed in subjects with spinal cord injury (SCI), despite the severity of their lesion, and that strong afferent input generated by ES-cycling and provided by patterened plantar cutaneous stimulation would increase spinal excitability
2. Use of the Soleus H-reflex reflex testing procedure before and after ES-cycling would reveal changes in spinal excitability that in turn would reflect both spinal and supraspinal motor control mechanisms after SCI

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité Ético de Investigación Clínica Complejo Hospitalario de Toledo (Ethics board of the clinical investigation of the Hospitals of Toledo), 26/06/2013, ref: 75

Study design
Randomised cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Non-injured participants and participants with incomplete SCI perform two test sessions on two different days with less than a two week interval between them. In the two sessions participants are asked to cycle for 10 minutes in a static ergometer with or without electrical stimulation of the right plantar foot, with the order randomised so that the order was presented equally to half of subject groups.
Participants are fitted with an ankle-foot orthosis to ankle movement and a movie is presented to distract the subjects during the study protocol. Cutaneoumuscular-conditioned Soleus H-reflex excitability is assessed immediately before and after each leg-cycling task, following a 10 minutes stimulus presentation to familiarise the participants. All cycling sessions are performed at 42 rpm and at an intensity comfortable to the participant, last for 10 minutes and are identical, except the innocuous stimulation applied to the plantar surface of the right foot with 1ms pulses delivered at 200Hz at the minimal intensity required to activate muscle contraction.

Electrical stimulation is applied only during the downstroke phase. During the leg cycling only test session, participants are blinded to the perceptual effect of electrical stimulation by applying this stimulus during the first minute of leg cycling. Cutaneomuscular-conditioned Soleus H-reflex excitability is tested with a preceding stimulus applied to the plantar foot at 25, 50, 75 or 100ms ISI. The innocuous stimulus train of five 1-ms pulses presented at 200Hz is applied with the protocol used in previous studies at an intensity just below that required to generate electromyographic TA reflex activity (80%). Soleus H-reflex activity is evoked with a 1ms electrical pulse delivered to the right tibial nerve by a superficial bipolar electrode applied on the popliteal fossa at a stimulation intensity required to generate an H-reflex at 50% of the maximum H-reflex amplitude. Reflex testing is performed with the right pedal fixed at 90° crank position, hip flexed at 70°, knee flexed at 20° and the ankle fixed in the neutral position 0° position. H-reflex activity was recorded 15 times for each testing condition (without plantar conditioning and at 25, 50, 75 and 100ms ISI) with a minimum test interval of 7s. Subjects with motor complete SCI participate as control group in the study. In their case, pedalling is assisted by electrical motors, and they only participate in the session that required cycling with combined electrical stimulation.

Intervention Type
Device

Primary outcome measure
1. Plantar cutaneous-conditioned H-reflex modulation is measured using electromyography on the Soleus muscle before and after each exercise execution
2. H-reflex amplitude is analyzed by measuring the amplitude of the H-reflex wave before and after each exercise execution

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2013

Completion date
01/06/2016

Eligibility

Key inclusion criteria
Inclusion criteria for non-injured subjects:
1. Age between 18 and 65
2. Not pregnant
3. Absence of neurological lesions
4. Availability to participate to the study
5. Tolerance of mild bursts of cutaneous electrical stimulation

Inclusion criteria for subjects with SCI:
1. Age between 18 and 65
2. Not pregnant
3. Availability to participate to the study
4. Tolerance of mild bursts of cutaneous electrical stimulation
5. Standard rehabilitation performed at the hospital

6. Neurological level of injury between C5 and T10
7. Less than 10 months from the time of SCI

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
28

Key exclusion criteria
1. Evidence or known history of epilepsy
2. Pregnancy
3. Evidence of lower limb musculoskeletal injury
4. Evidence of peripheral nervous system disorders

Date of first enrolment
17/01/2014

Date of final enrolment
30/05/2015

Locations

Countries of recruitment
Spain

Study participating centre
National Paraplegics Hospital of Toledo (Hospital Nacional de Paraplejicos de Toledo)
Finca La Peraleda
Toledo
Spain
45071

Sponsor information

Organisation

National Hospital for Paraplegics in Toledo (Hospital Nacional de Parapléjicos de Toledo)

Sponsor details
Finca La Peraleda, s/n
Toledo
Spain
45071

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04xzgfg07

Funder(s)

Funder type
Government

Funder Name
Ministerio de Ciencia e Innovación

Alternative Name(s)
CienciaGob, Ministerio de Ciencia e Innovación de España, Ministry of Science and Innovation, Spanish Ministry of Science and Innovation, Ministry of Science and Innovation of Spain, Spain, Ministry for Science and Innovation, Ministeri de Ciència i Innovació, MCIN, MICINN

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018		Yes	No