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Comparison of walking quality between incomplete spinal cord injury patients and healthy subjects using a Footscan plantar pressure system

Submission date
10/08/2018

Recruitment status
No longer recruiting

Registration date
22/08/2018

Overall study status
Completed

Last Edited
12/12/2018

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
In the majority of spinal cord injury (SCI) patients who retain some walking ability, movement is often limited to the confines of their homes or short distances, and patients are often dependent upon the assistance of devices or their caregivers. Therefore, one of the main focuses of rehabilitation for these patients is the recovery of the ability to walk well. Good walking quality includes walking fast and walking symmetrically. It is possible to obtain quantitative data about the walking ability of these patients, which can be used to help with recognition of the underlying causes and development of pathological gaits (walking abnormalities). This study aims to use a device called the Footscan plantar pressure system to collect this walking data to determine the differences in walking quality between SCI patients and healthy subjects.

Who can participate?
Healthy adults with a spinal cord injury

What does the study involve?
Participants will be asked to walk in bare feet upon the Footscan platform at a comfortable speed for at least 2 times to familiarise themselves with the device and then 3 times to test their walking quality after resting.

What are the possible benefits and risks of participating?
The benefit of participating in this trial is that patients will receive a report about their walking quality (plantar pressure and gait). There are no known risks to participants taking part in this study.

Where is the study run from?
Rehabilitation Department of Shengjing Hospital of China Medical University. (China)

When is the study starting and how long is it expected to run for?
October 2013 to March 2017

Who is funding the study?
Shengjing Hospital of China Medical University (China)

Who is the main contact?
Dr Xiangnan Yuan
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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
1.0

Study information

Scientific Title
The effects of the Footscan plantar pressure plate system on walking quality variables between spinal cord injury patients and healthy subjects

Study objectives
Compared with healthy subjects, there will be a difference in variables of gait and an asymmetry of gait quality in spinal cord injury patients, including step length and the variables of plantar pressure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee of Shengjing Hospital of China Medical University, 13/08/2015, No. 2015PS54J

Study design
Observational prospective cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

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

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

Interventions
The subjects were asked to walk in bare feet upon the footscan platform at their comfortable speed. Each subject undertook at least 2 practice walks along the plate walkway in order to familiarize themselves with, and hence feel at ease with, the experimental process. Following an adequate recuperation period, each subject was asked to walk in bare feet upon the footscan platform at their comfortable speed for at least 3 successful trials. Subjects reporting fatigue were permitted to rest for a minimum of 2 minutes between trials.

Intervention Type
Behavioural

Primary outcome measure
Walking speed, measured through participants walking on the the Footscan platform at their comfortable speed for at least 3 successful trials on the day of participation.

Secondary outcome measures
The following were measured on the day of participation by participants walking on the the Footscan platform at their comfortable speed for at least 3 successful trials:
1. Stride time in seconds
2. Stride length in metres
3. Stance time in seconds
4. Step length in metres
5. Peak plantar pressure in Newtons per cm^2
6. Impulse in Newtons per second

7. Maximum force in Newtons
8. Contact area percentage

Overall study start date
01/10/2013

Completion date
01/03/2017

Eligibility

Key inclusion criteria
Spinal cord injury group:
1. Complete spinal cord injury (SCI) according to American Spinal Cord Injury Association (ASIA) Impairment Scale (AIS)
2. Capacity for independent walking, with or without mechanical support, for a minimum of 15 minutes

Healthy subjects:
1. None of the aforementioned conditions
2. Matching age (± 5 years) and sex to participants in SCI group

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
51

Key exclusion criteria
Spinal cord injury group:
1. Severe spasticity of the lower extremity muscles, rated as greater than or equal to 2 on the Modified Ashworth Scale (MAS)
2. Muscle or joint pain with an intensity rating of greater than 5 out of 10 on a numerical scale
3. Presence of cognitive or behavioural disorders
4. Spinal or lower extremity deformities, such as scoliosis, kyphosis or equinovarus
5. Clinical instability

Healthy subjects:
1. Muscle or joint pain of low extremities or spine
2. Presence of cognitive disorders
3. Flat foot
4. Cavus foot
5. Abnormal gait

Date of first enrolment

01/08/2015

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
China

Study participating centre
Shengjing Hospital of China Medical University
No.36, Sanhao Street, Heping District
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110004

Sponsor information

Organisation
Shengjing Hospital of China Medical University

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0202bj006

Funder(s)

Funder type
Not defined

Funder Name

the New Technique Project of Shengjing Hospital of China Medical University, China, No. 117

Results and Publications

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

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Xiangnan Yuan (e-mail is yuanxn@sj-hospital.org). Plantar pressure data will become available after the study results are published and will be available for 1 year.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019		Yes	No