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Early respiratory therapy and rehabilitation interventions in the role of the prognosis of patients with acute traumatic spinal cord injury

Submission date
30/09/2017

Recruitment status
No longer recruiting

Registration date
10/10/2017

Overall study status
Completed

Last Edited
09/10/2017

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The spinal cord is a soft bundle of nerves that extends from the base of the brain to the lower back, through which the brain sends movement commands and receives sensory information. Spinal cord injury (SCI) is a catastrophic event associated with disruptions to the movement, sensory, cardiovascular (heart), and respiratory (breathing) systems. The aim of this study is to assess the effects of SCI on breathing function and the muscle power of the limbs, and whether treatment reverses these changes during the 6-month follow-up period.

Who can participate?
Acute Spinal Cord Injury (SCI) patients aged 20-70

What does the study involve?
Patients participate in a 12-week exercise rehabilitation program at least three times per week for 20 to 30 minutes, and a 12-week respiratory (breathing) muscle training program. At the start of the study and after 2 weeks, 1 month, 3 months and 6 months, participants undergo measurements including: breathing function, muscle power, heart rate, blood pressure, blood tests and brain MRI scans.

What are the possible benefits and risks of participating?
The blood test may cause short-term discomfort, bleeding or swelling. The other tests are not invasive and do not involve any risks for the patient.

Where is the study run from?
Chang Gung Memorial Hospital - Kaohsiung Branch (Taiwan)

When is the study starting and how long is it expected to run for?
February 2015 to January 2018

Who is funding the study?
Chang Gung Memorial Hospital, Linkou (Taiwan)

Who is the main contact?
Dr Hung-Chen Wang
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CMRPG8D1391

Study information

Scientific Title
Early aggressive respiratory therapy and rehabilitation interventions in the role of the prognosis of patients with acute traumatic spinal cord injury and explore oxidative stress, inflammation, DNA damage, leukocyte apoptosis and endothelial dysfunction, and its association with cardiovagal function and cerebral autoregulation

Study objectives
Hypothesis: Endothelial oxidative stress and inflammation are increased, endothelium repair capacity are reduced, leukocyte apoptosis are decreased, and decreased gain of baroreflex sensitivity and cerebral autoregulation in patients with acute SCI compared with healthy subjects, and treatment reverses these biomarkers alterations, and changes of baroreflex sensitivity and cerebral autoregulation during the 6-month follow-up period.

The study will also explore which signaling pathways involved in the apoptosis of EPCs. The successful translation of these approaches to the clinics offers the promise of not only predicting the outcome but also assessing the impact of these factors on therapeutic efficacy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Chang Gung Memorial Hospital (TAIWAN), 13/01/2015, ref: 103-5218B

Study design
Single-centre interventional longitudinal case-control study

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
Acute spinal cord injury

Interventions
Rehabilitation treatment: Patients participated in a 12-week exercise program. They performed mobility, strength, range of motion, aerobic resistance, and ambulation training. A minimum exercise frequency of 3 times per week and a minimum duration of 20 to 30 minutes, and an exercise intensity of 70% to 80% of heart rate reserve is necessary to produce training effects.

Respiration treatment: Patients participated in a 12-week respiratory muscle training (RMT) program, including maximal expiratory pressure (MEP) and maximal inspiratory pressure (MIP) monitor.

Intervention Type
Device

Primary outcome measure
Measured at baseline, 2 weeks, 1 month, 3 months and 6 months:
1. Mechanical ventilation free rate (no mechanical ventilator used) at discharge
2. Respiratory function:
2.1. Maximal inspiratory pressure (MIP) measured with a pressure manometer
2.2. Maximal expiratory pressure (MEP) measured with a pressure manometer
2.3. Rapid shallow breathing index (RSBI, respiratory rate/tidal volume) measured using

Haloscale
3. Muscle power of limbs, measured using Japanese Orthopaedic Association (JOA) cervical spine myelopathy functional assessment score

Secondary outcome measures
Measured at baseline, 2 weeks, 1 month, 3 months and 6 months:
1. Endothelial oxidative stress, measured using ELISA
2. DNA damage, measured using RT-PCR
3. Inflammation, measured using ELISA
4. Leukocyte apoptosis, measured using a flow cytometic assay
5. Circulating endothelial progenitor cells (EPCs), measured using a flow cytometric method
6. Baroreflex sensitivity, measured using Valsalva maneuver and sequence method
7. Cerebral autoregulation, measured using Arterial Spin Labeling (ASL) MRI

Overall study start date
01/02/2015

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. Acute Spinal Cord Injury (SCI) patients aged 20-70 years old
2. Patients will be enrolled in this study only if full informed written consent is obtained from the patient or their families and they qualify for the above-mentioned diagnostic criteria. The informed written consent will be approved by the Ethics Committee

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Severe multiple trauma with unstable hemodynamic status
2. Previous brain insults, such as stroke, traumatic intracranial hemorrhage, meningitis, or degenerative brain diseases that cause central nerve system abnormality
3. Infection or inflammation status before admission
4. Diffuse atherosclerotic changes on extracranial vessels; hematologic disorders that affect leukocyte, platelet count, or function
5. Taking antiplatelet or anticoagulation drugs
6. Major systemic disease, such as end-stage renal diseases, liver cirrhosis, and congestive heart failure

Date of first enrolment
21/04/2015

Date of final enrolment
31/01/2018

Locations

Countries of recruitment
Taiwan

Study participating centre
Chang Gung Memorial Hospital - Kaohsiung Branch
Kaohsiung
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83305

Sponsor information

Organisation
Chang Gung Memorial Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02verss31

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Chang Gung Memorial Hospital, Linkou

Alternative Name(s)
Linkou Chang Gung Memorial Hospital

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Taiwan

Results and Publications

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

Intention to publish date
31/01/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other