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Acupuncture-induced mobilization of neurogenic stem cells

Submission date	Recruitment status
05/02/2019	No longer recruiting
Registration date	**Overall study status**
18/02/2019	Completed
Last Edited	**Condition category**
18/02/2019	Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
The aim of this study is to measure cellular mechanisms before and after acupuncture treatment in patients with traumatic spinal cord injuries. The cellular mechanisms measured are possibly responsible for regeneration of the spinal cord.

Who can participate?
Patients aged 18-60 with traumatic spinal cord injuries

What does the study involve?
Participants undergo 15 acupuncture treatments consisting of the manual stimulation of 11 acupuncture points. Before and after each treatment blood samples are taken. Also, before the first and after the last acupuncture, neurological functions are tested by experienced examiners and classified according to the American Spinal Injury Association. Their quality of life is monitored with a standardized questionnaire.

What are the possible benefits and risks of participating?
Benefits are acupuncture treatments and two additional neurological examinations. Risks include local bruising due to acupuncture needles and taking blood samples. Changes in blood pressure may occur.

Where is the study run from?
Patients were recruited in Bayreuth and Erlangen, blood analyses are performed in Berlin, Ludwigshafen and Mannheim, Germany.

When is the study starting and how long is it expected to run for?
September 2010 to March 2015

Who is funding the study?
The study was funded by the German Medical Association for Acupuncture and the Chinese Scientific Council

Who is the main contact?
1. Dr Sonja Moldenhauer
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Contact information

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Additional identifiers

Protocol serial number
2009/112

Study information

Scientific Title
Acupuncture-induced mobilization of CD133(+) 34(-) neuroprogenitors in patients with spinal cord injuries

Acronym

AIMNP

Study objectives
Manual acupuncture induces an increase of neuroprogenitors in patients with spinal cord injuries leading to a clinical improvement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
2007: Charité - Univeristätsmedizin Berlin EA2/095/2007
2008: Ethics Committee of the Bavarian Medical Chamber Munich, 7/08111

Primary study design
Interventional

Study design
Pilot single-center non-controlled non-randomized study

Study type(s)
Treatment

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

Interventions
Four patients were treated 15 times with manual acupuncture twice per week over a period of 2 months. Before and after each acupuncture, differential blood counts, the number of CD133(+) 34(-) and CD34(+) cells as well as CD14(+) and CD4(+) cells, brain-derived neurotrophic factor (BDNF) and matrix metalloproteinase (MMP) 9 concentrations were determined. Before and after the treatment period ASIA scores were determined to assess sensor and motor functions and their quality of life was assessed.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Mobilization of CD133(+)34(-) cells) measured by flow cytometry of whole blood before and after each acupuncture treatment (30 times per patient)

Key secondary outcome(s)
Before the first (baseline) and after the last acupuncture (15th):
1. Quality of life measured by SF-36
2. Clinical changes measured by ASIA scores

Completion date
15/03/2015

Eligibility

Key inclusion criteria
Spinal cord injuries for at least 6 months, ASIA score A

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Need for mechanical ventilation and history of stroke, transient ischemic attack, epilepsy, Parkinson’s disease, multiple sclerosis, bleeding diathesis, cardiovascular diseases, severe diabetes, fever, chronic diarrhea, or severe mental disorders during the preceding 6 months

Date of first enrolment
01/10/2011

Date of final enrolment
11/03/2013

Locations

Countries of recruitment
Germany

Study participating centre
Charite - Universitätsmedizin Berlin
Department of Psychiatry and Psychotherapy
Charitéplatz 1
Berlin
Germany
10117

Study participating centre
Klinikum der Stadt Ludwigshafen
Institute for Hemostaseology and Transfusion Medicine
Bremserstr. 79
Ludwigshafen
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Study participating centre
Klinikum Hohe Warte
Department of Neurology
Hohe Warte 8
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95445

Study participating centre
Clinic for Acupuncture
Dompfaffstr. 123
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University of Applied Sciences Mannheim
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Sponsor information

Organisation
German Medical Acupuncture Association

Organisation
China Scholarship Council

Funder(s)

Funder type
Research organisation

Funder Name

German Medical Acupuncture Association

Funder Name
China Scholarship Council

Alternative Name(s)
CSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sonja Moldenhauer (sonja.moldenhauer@gmx.de).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2010		Yes	No