

# Acupuncture-induced mobilization of neurogenic stem cells

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<b>Registration date</b> 18/02/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/02/2019	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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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2. Dr Anja Moldenhauer  
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## Contact information

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Scientific

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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

### **Study design**

Pilot single-center non-controlled non-randomized study

### **Primary study design**

Interventional

### **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

Germany

67063

**Study participating centre**  
**Klinikum Hohe Warte**  
Department of Neurology  
Hohe Warte 8  
Bayreuth  
Germany  
95445

**Study participating centre**  
**Clinic for Acupuncture**  
Dompfaffstr. 123  
Erlangen  
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91056

**Study participating centre**  
**University of Applied Sciences Mannheim**  
Paul-Wittsack-Straße 10  
Mannheim  
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68163

## **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?
<a href="#">Results article</a>	results	01/06/2010		Yes	No