

Acupuncture-induced mobilization of neurogenic stem cells

Submission date
05/02/2019

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
18/02/2019

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
18/02/2019

Condition category
Injury, Occupational Diseases, Poisoning

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 - Universitätsmedizin 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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

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 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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2010

Completion date

15/03/2015

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

4

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

Sponsor details

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81375 München

Munich

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81375

089 7100511

wissenschaftszentrum@daegfa.de

Sponsor type

Research organisation

Website

<https://www.daegfa.de>

Organisation

China Scholarship Council

Sponsor details

No. 9 Chegongzhuang Ave.

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100044

86 10 66093900

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Sponsor type

Government

Website

<https://www.csc.edu.cn/>

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

Publication and dissemination plan

The data on healthy volunteers has already been published. The ex vivo generation of neural cells from acupuncture patients is accepted for publication. The trialists plan to publish the results in the near future.

Intention to publish date**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