

Acupuncture as a disease modifying therapy for the treatment in remission stage of neuromyelitis optics spectrum disorders

Submission date 21/11/2016	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 22/12/2016	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 22/12/2016	Condition category Nervous System Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Neuromyelitis Optica Spectrum Disorder (NMOSD) is a rare condition that affects the optic nerves and spinal cord. It is an autoimmune condition, which means that the body's immune system attacks healthy tissue leading to inflammation (swelling). An antibody against a protein called aquaporin-4 is present in the blood of up to 80% of people with NMOSD, which attacks aquaporin-4, leading to damage to the myelin sheath (the protective layer that surrounds nerve cells in the brain and spinal cord and helps transmit nerve signals). Over time, sufferers experience periods of lower disease activity (remission) and bouts where symptoms become much worse (relapse). In order to maintain remission, drugs that suppress the immune system, such as Azathioprine can be used. Acupuncture is an ancient Chinese medical technique which can be used to effectively treat a number of conditions. The aim of this study is to find out whether treatment with Azathioprine and acupuncture is more effective than treatment with Azathioprine alone in treating NMOSD.

Who can participate?

Patients with NMOSD in relatively stable stage of disease.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are treated with a therapeutic dose of medicine (Azathioprine) for three months. Those in the second group are treated with Azathioprine for three months as well as receiving acupuncture three times a week for two weeks a month for three months. At the start of the study and then again after three, six and 12 months, participants have a blood sample taken which is tested for antibody levels as well as having their level of disability assessed.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to those taking part, but there should be benefits to future NMOSDs patients and also to the disease itself because the results of the study are likely to influence how NMOSDs is treated and broaden the method of treatments available. Patients can also get disease related counseling. The main risks of acupuncture are fainting, infection,

pneumothorax (abnormal collection of air in the space around the lungs) and sticking of the needle. Therefore, the Acupuncture Centre will continue to follow its routine safety procedures while practicing acupuncture.

Where is the study run from?

Beijing Traditional Chinese Medical Hospital affiliated to Capital University (China)

When is study starting and how long is it expected to run for?

April 2016 to December 2018

Who is funding the study?

Beijing Municipal Hospital Authority (China)

Who is the main contact?

Dr. Chunchen Wang

Contact information

Type(s)

Public

Contact name

Miss Chunchen Wang

Contact details

Beijing Traditional Chinese Medical Hospital Affiliated to Capital Medical University

Meishuguan Hou Street No.23

Dongcheng District

Beijing

China

100010

Additional identifiers

Study information

Scientific Title

Acupuncture as a disease modifying therapy for treatment in remission stage of neuromyelitis optica spectrum disorders: a prospective clinical randomised parallel trial

Study objectives

Acupuncture is better than Azathioprine as a treatment in remission stage of neuromyelitis optica spectrum disorders.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethics Committee of Beijing Traditional Chinese Medicine Hospital affiliated to Capital Medical University. 14/03/2016, ref: 2016BL-019-01

Primary study design

Interventional

Study design

Single-centre prospective randomised parallel trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Neuromyelitis optica spectrum disorders of remitting stage

Interventions

Participants are randomised to one of two groups using a computerised random number table.

Intervention group: Participants are treated with oral azathioprine at a dose of 2mg/Kg-D for three months in addition to receiving manual acupuncture three times a week, two weeks a month.

Accupoints used include:

Jiaji acupoints: back to the first thoracic lumbar spine to the fifth lumbar spine on both sides, after the middle of the midline beside 0.5 inches, one side of the 17 points, a total of 34 points on both sides

Hand and foot twelve acupoints: ShangWan, ZhongWan, XiaWan, TianShu, GuanYuan, NeiGuan, ZuSanLi

Add acupuncture points according to the accompanying symptoms:

Decreasing of visual acuity : CuanZhu , JingMing, fengchi , QiuHou, GuangMing

Dysphagia : LianQuan , FengChi , WanGu, YiFeng

Urinary disorders : ShuiDao, Cilia, Zhongji

Dysphoria: Tianshu, Zhongwan, Qihai

Control group: Participants are treated with oral azathioprine at a dose of 2mg/Kg-D for three months only.

Participants in both groups are followed up after three months, six months and one year.

Intervention Type

Other

Primary outcome(s)

Disability is measured using the Expanded disability scale score at baseline, 3, 6 and 12 months.

Key secondary outcome(s)

1. AQP4-IgG level is measured using cell transfection method at baseline and 3 months
2. Annual relapse rate is measured using computer formula at baseline, 3, 6 and 12 months

Completion date

28/12/2018

Eligibility

Key inclusion criteria

1. Diagnosis of neuromyelitis optica spectrum disorders in accordance with NMOSDs diagnostic criteria established by the international panel for NMO diagnosis (IPND) in 2015.
2. In remission stage (no acute progress, no corticosteroid therapy or immunoglobulin therapy, plasma exchange, stable condition without relapse signs)
3. Age of 18-75 years old
4. EDSS score less than 5
5. No other treatment with immunosuppressive drugs within 6 months or no other immunosuppressive drugs other than azathioprine
6. Provision of informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

18 Years

Upper age limit

75 Years

Sex

All

Key exclusion criteria

1. Oral azathioprine intolerant patients
2. History of severe allergies
3. Those who can not tolerate acupuncture
4. Clinically significant history of disease, blood disease, endocrine, metabolism, liver, lung, urinary system, nervous system, skin disease, other major primary disease and psychiatric disease
5. Malignant tumor
6. B type hepatitis
7. Pregnancy or lactation

Date of first enrolment

01/04/2016

Date of final enrolment

28/09/2017

Locations**Countries of recruitment**

China

Study participating centre

Beijing Traditional Chinese Medical Hospital affiliated to Capital University

Meishuguan Hou Street No.23

Dongcheng district

Beijing

China

100010

Sponsor information

Organisation

Beijing Traditional Chinese Medical Hospital Affiliated to Capital Medical University

ROR

<https://ror.org/057vq6e26>

Funder(s)

Funder type

Government

Funder Name

Beijing Municipal Hospital Authority

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary

Other