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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

Registration date
22/12/2016

Overall study status
Completed

Last Edited
22/12/2016

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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 motnhs, 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NA

Study information

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

Study objectives

Acupuncture is better than Azathioprine as a treatment in remission stage of neuromyelitis optics 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

Study design
Single-centre prospective randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Neuromyelitis optics 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 measure
Disability is measured using the Expanded disability scale score at baseline, 3, 6 and 12 months.

Secondary outcome measures
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

Overall study start date
20/12/2016

Completion date
28/12/2018

Eligibility

Key inclusion criteria
1. Diagnosis of neuromyelitis optics 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

Age group
Child

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
40 NMOSDs patients of remitting stage

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

Sponsor details
Meishuguan Hou Street No.23
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Government

Funder Name
Beijing Municipal Hospital Authority

Results and Publications

Publication and dissemination plan
The results of this study are intended to be published in a peer reviewed journal.

Intention to publish date
30/06/2019

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