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Can acupuncture affect cytokine levels in multiple sclerosis?

Submission date
22/10/2020

Recruitment status
No longer recruiting

Registration date
02/11/2020

Overall study status
Completed

Last Edited
16/07/2021

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is a condition affecting the brain and spinal cord that causes problems with vision, arm or leg movement, sensation or balance. Cytokines have been found to play a role in the disease activity of MS. Previous studies indicate that acupuncture can affect cytokine levels in persons with other inflammatory diseases. The aim of this study is to investigate the effect of acupuncture on cytokine levels and health-related quality of life in patients with MS.

Who can participate?
Patients aged 18 or older with relapsing-remitting MS (RRMS) for at least 2 years, who have not changed disease-modifying treatment within the past 3 months and have not received acupuncture treatment within the past 3 months.

What does the study involve?
Participants will be randomly allocated to receive either real acupuncture, sham acupuncture or no acupuncture. The patients receiving acupuncture will receive a total of six treatments over a period of 4 weeks: two treatments in each of the first 2 weeks and one treatment in each of the following 2 weeks. Measurements will be taken at baseline, the day after the 4th treatment, the day after the final treatment, and at 4 weeks after the final treatment.

What are the possible benefits and risks of participating?
Participants will contribute to important research that may enhance the health and quality of life of themselves and other persons with MS. Acupuncture is generally a safe treatment associated with little or no side-effects. The following side-effects may occur: bruises and discomfort around the needling points. More rarely seen side-effects include nausea, malaise, drowsiness, a feeling of elation, dizziness and fainting. At the beginning of the treatment, symptoms may temporarily worsen. Blood sampling may cause small bruising and discomfort around the point of needle insertion. There is a minimal risk of infection in relation to blood sampling.

Where is the study run from?
The study is run from the Danish MS Society in cooperation with the Institute of Immunology and Microbiology at the University of Copenhagen (Denmark)

When is the study starting and how long is it expected to run for?
August 2016 to November 2017

Who is funding the study?
Danish National Board of Health and the Danish MS Society (Denmark)

Who is the main contact?
Lasse Skovgaard
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of acupuncture on cytokine levels in persons with multiple sclerosis: a randomized controlled trial

Study objectives

Cytokines have been found to play a role in disease activity in Multiple Sclerosis (MS), and studies indicate that acupuncture can affect cytokine levels in people with other inflammatory diseases. It is hypothesized that acupuncture will affect cytokine levels in the intervention group which will not be seen in the control groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/03/2017, The Danish Committee on Health Research Ethics (Ørestads Boulevard 5, bygn. 37K, st., 2300 København S, Denmark; +45 (0)72 21 68 55; vek@regionh.dk), ref: H-17004731

Study design
Single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet (in Danish)

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
Participants are randomized into three groups: an intervention group receiving real acupuncture, a control group receiving sham acupuncture, and a second control group receiving no acupuncture. A simple randomization approach is used in which participants are assigned a random number between 0 and 1 using the Microsoft Excel RAND function. They are then placed in order from lowest to highest number and finally divided into groups in that order.

The acupuncture treatments are performed by two practitioners with university degrees in TCM as well as in Western medicine and the sessions take place in the clinics of the two acupuncturists.

Each patient from the two treatment groups (real acupuncture and sham treatment) receive a total of six treatments over a period of 4 weeks: two treatments in each of the first 2 weeks and one treatment in each of the following 2 weeks.

A standardized TCM treatment using ten acupuncture points has been developed to specifically target inflammation levels. The chosen acupuncture points are GV20, CV6, BL23 (bilateral), LI4 (bilateral) ST36 (bilateral), and SP6 (bilateral). These ten points are used in each treatment session in both treatment groups. Needles will be removed after 40 minutes, except for BL23 which will be removed after 20 minutes.

Streitberger Placebo needles will be used for the sham treatment.

In addition to the standard treatment, the acupuncturists can place additional needles to target specific symptoms reported by the participant. Any additional needles are removed after 20 minutes.

Intervention Type
Other

Primary outcome measure
Cytokine plasma levels (IFNγ, IL-1β, IL-6, IL-8, IL-12p70, IL-13, TNFα, IL-10, IL-4, IL-2 and IL-17A) measured using the Mesoscale Multi-spot Assay System on blood samples taken at baseline, the day after the 4th treatment, the day after the final treatment, and at 4 weeks following the final treatment

Secondary outcome measures
Health-related quality of life (HRQoL) measured using the MS-specific Functional Assessment of Multiple Sclerosis (FAMS) instrument at baseline, after 4 weeks (following the last treatment), and at 4 weeks after the final treatment

Overall study start date
01/08/2016

Completion date
07/11/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Diagnosed with relapsing-remitting multiple sclerosis for a minimum of 2 years
3. Must be able to walk unassisted (equivalent to an EDSS of 6.5)
4. Must have been relapse-free for the past 3 months
5. If treated with disease-modifying medicine, treatment must have been unchanged for the past 3 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
66

Key exclusion criteria
1. Significant co-morbidities (heart disease, diabetes, Mb. Crohn or other) which may affect the immune system
2. Has received acupuncture treatment within the past 3 months

Date of first enrolment
01/05/2017

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
Denmark

Study participating centre
The Danish MS Society
Poul Bundgaards Vej 1
Valby
Denmark
2500

Sponsor information

Organisation
Scleroseforeningen

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Sponsor type
Charity

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https://scleroseforeningen.dk/

ROR
https://ror.org/037s01565

Funder(s)

Funder type
Government

Funder Name
Sundhedsstyrelsen

Alternative Name(s)
Danish Health and Medicines Authority, DHMA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Denmark

Funder Name
Scleroseforeningen

Alternative Name(s)
Danish Multiple Sclerosis Society, Danish MS Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Denmark

Results and Publications

Publication and dissemination plan
Study results will be published in a scientific peer-reviewed journal specializing in traditional and complementary treatment

Intention to publish date
01/11/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the researchers don’t have a platform from which to share the data. The data is held by the Danish MS Society.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			06/11/2020	No	No
Results article		15/07/2021	16/07/2021	Yes	No