ISRCTN82980206 https://doi.org/10.1186/ISRCTN82980206

Effect of acupuncture treatment on Vascular Cognitive Impairment, No Dementia

Submission date
13/11/2013

Recruitment status
No longer recruiting

Registration date
17/01/2014

Overall study status
Completed

Last Edited
06/03/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Cerebrovascular disease (conditions that are a result of problems with the blood vessels in the brain) and ischemic brain injury caused by heart disease are common causes of dementia and decline in cognitive (mental) function in the elderly. Reduced mental function without dementia (vascular cognitive impairment, no dementia [VCIND]) comprises a range of cognitive disorders related to cerebral vessel disease. A study on the progression of cognitive and functional impairment showed that 2% of VCIND patients died and 46% developed dementia. Unlike many other cognitive disorders, VCIND could be prevented or the course of cognitive decline could be improved. However, apart from controlling vascular risk factors, the effects of drug treatment on patients with VCIND are uncertain. Acupuncture is widely used for patients with neuropsychiatric disorders but there is a lack of information about its effectiveness. The aim of this study is to assess the effectiveness of acupuncture in the treatment of VCIND patients.

Who can participate?
Male and female patients aged 50-85 diagnosed with VCIND.

What does the study involve?
Participants will be randomly allocated to receive either acupuncture or a drug. The acupuncture group will receive two acupuncture sessions per week for 3 months. The drug group will be treated with oral citicoline three times per day for 3 months.

What are the possible benefits and risks of participating?
The results of this study may contribute to the future improvement of patient care. Participants may benefit from improved functional status and quality of life. The risks of taking part are minimal. Citicoline has been recommended in some European countries with a reliable safety profile. Acupuncture is a relatively safe treatment when given by properly trained clinicians. Occasionally acupuncture could make people feel nauseous or faint during or after treatment. Participants are warned of potential side effects before consenting to have the drug or acupuncture.

Where is the study run from?
This study will be carried out at four different centers in China: Beijing Hospital of Traditional

Chinese Medicine affiliated to Capital Medical University, Beijing Chinese Medicine Hospital in Huairou District, the Beijing Fengtai Hospital of Integrative Medicine, and Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine.

When is the study starting and how long is it expected to run for?
The study started in July 2013 will be recruiting patients until December 2015. The study is expected to complete in October 2016.

Who is funding the study?
Beijing Municipal Science & Technology Commission (China).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
z131107002213034

Study information

Scientific Title
Effect of acupuncture treatment on Vascular Cognitive Impairment, No Dementia: a multi-center, randomized, controlled trial

Acronym
VCIND

Study objectives
To investigate the effect of acupuncture on vascular cognitive impairment no dementia (VCIND).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, 22/03/2013, ref: 201317

Study design
Multi-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Vascular cognitive impairment not dementiaVCIND

Interventions
All participants will be randomized to two different groups:
1. Acupuncture group: this group of patients will receive two acupuncture sessions per week for 3 months.
2. Drug group: this group of patients will receive oral citicoline 0.1g per time, 3 times per day for 3 months.

Intervention Type
Mixed

Primary outcome measure
The cognitive section of the Alzheimer Disease Assessment Scale (ADAS-Cog) will be assessed at baseline, the end of treatment and 3 months after the end of treatment.

Secondary outcome measures

1. Clock drawing test (CDT) will be assessed at baseline, the end of treatment and 3 months after the end of treatment.
2. Ability of daily living (ADL) and instrumental activities of daily living scale (IADL) will be assessed at baseline, the end of treatment and 3 months after the end of treatment.

Participants will report adverse events they experience, including discomfort or bruising at the sites of needle insertion, nausea, or feeling faint after each acupuncture treatment. Adverse drug reactions like nausea and vomiting, dizziness, dry mouth and itching will also be recorded.

Overall study start date
01/07/2013

Completion date
30/10/2016

Eligibility

Key inclusion criteria
1. Aged 55-85 years, either sex
2. Hachinski score ≥7
3. Evidence of vascular lesions on neuroradiology
4. Fluency in language sufficient to reliably complete all study assessments
5. Mini-Mental State Examination (MMSE) score >dementia threshold corrected based on educational year (>17 scores, >20 scores and >24 scores for 0, ≤6, and>6 educational years, respectively)
6. Montreal Cognitive Assessment (MoCA) <26 scores for >12 educational years (or <25 scores for≤12 educational years)
7. Written and informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
216

Key exclusion criteria
1. History of mental diseases (e.g., schizophrenia, serious anxiety and depression)
2. Patients with Alzheimer's disease, Parkinson's disease, frontotemporal dementia or Huntington's disease
3. Patients with epilepsy and/or ever having antiepileptic drugs
4. Presence of serious heart diseases, kidney diseases or liver diseases

Date of first enrolment
01/07/2013

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University
Beijing
China
100010

Sponsor information

Organisation
Beijing Municipal Science & Technology Commission (China)

Sponsor details
No. 7, Building 2
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Sponsor type
Government

Website
http://www.bjkw.gov.cn/n8785584/index.html

ROR
https://ror.org/034k14f91

Funder(s)

Funder type
Government

Funder Name
Beijing Municipal Science & Technology Commission (China)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

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 Cun-Zhi Liu (lcz623780@126.com). The data will become available from the publication of the article to a year later. All subjects' data will be shared including with all participants, as electronic documents, and by e-mail.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/11/2014		Yes	No
Results article	results	01/04/2019	18/02/2019	Yes	No