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Acupuncture treatment of breast cancer after chemotherapy in patients with cognitive impairment caused by 'disorder of qi and blood': a randomized single-blind study

Submission date
10/12/2014

Recruitment status
No longer recruiting

Registration date
25/03/2015

Overall study status
Completed

Last Edited
25/03/2015

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In recent years, the treatment of cognitive dysfunction caused by breast cancer chemotherapy has received more and more attention. The purpose of this study is to determine whether acupuncture is effective in managing patients with cognitive impairment after chemotherapy for breast cancer.

Who can participate?
Women aged between 25-55 years old with a history of breast cancer who have been treated with chemotherapy and with evidence of cognitive dysfunction.

What does the study involve?
Participants will be randomly allocated to one of two groups: the treatment group or the control group. Women in the treatment group will be given acupuncture twice a week for 2 months. The control group will be given acupuncture at five feint (dummy) points twice a week for 2 months. Participants will complete questionnaires at the start of the study and every month after that to find out about changes in cognitive function, intelligence and quality of life. Participants will undergo certain tests before and after treatment in order to find out the safety and effectiveness. Participants will be followed up after two months and four months to assess long-term effectiveness.

What are the possible benefits and risks of participating?
All participants will receive free treatment for 2 months and a series of free tests. The symptoms of the cognitive dysfunction could be relieved. The results of this study may help to provide evidence that acupuncture treatment of cognitive impairment is safe and effective. You have to visit the hospital regularly, which may be inconvenient and may disturb your routine. Acupuncture treatment can lead to curved needle, needle breakage, and adverse reactions such

as subcutaneous hematoma. Therefore, at the same time as acupuncture therapy a safety assessment will be carried out. If there is a threat to personal safety we will immediately stop acupuncture and take the appropriate treatment measures.

Where is the study run from?
Participants are recruited at Beijing Hospital of Traditional Chinese Medicine, China.

When is study starting and how long is it expected to run for?
October 2014 to September 2015.

Who is funding the study?
Beijing Hospital of Traditional Chinese Medicine, China.

Who is the main contact?
Dr Qing Zhang
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2014GG-19

Study information

Scientific Title
Randomized, single-blind, sham acupuncture-controlled trial of acupuncture treatment of breast cancer after chemotherapy in patients with cognitive impairment caused by 'disorder of qi and blood'

Study objectives
The purpose of this study is to determine whether acupuncture is effective in managing patients with cognitive impairment after chemotherapy for breast cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration – submission pending

Study design
Randomised single-blinded placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Breast cancer after chemotherapy in patients with cognitive impairment

Interventions
The 100 eligible participants are randomly allocated to two different groups:
1. Treatment group: acupuncture will be given at Zusanli (ST 36) PointXuhai PointTanzhong Point Zhongwan PointQihai (CV 6) PointBaihui(GV 20) PointFengfu PointXinshu(bl 15) PointYixi (bl 45) PointTongli (ht 5) Point and Zhaohai (KI 6) Point twice a week for 2 months. The patients receive assessments every month during the treatment and the second month and the fourth month after the treatment.
2. Control group: acupuncture will be given at five feint points twice a week for 2 months.

Intervention Type
Other

Primary outcome measure
Using the Montreal Cognitive Assessment MoCAto assess cognitive function. To observe the cognitive ability of patients with breast cancer after chemotherapy with cognitive dysfunction. The outcome measure above will be assessed before the treatment, at 1 month and 2 months during the treatment; the assessments will be repeated at the second and fourth months after the treatment.

Secondary outcome measures

1. Using the Mini-mental State Examination to assess immediate memory, attention, computing power, etc.
2. Using the EORTC QLQ-30 to assess the quality of life.
The outcome measures above will be assessed before the treatment, at 1 month and 2 months during the treatment; the assessments will be repeated at the second and fourth months after the treatment.
3. Safety assessment. Acupuncture treatment can lead to curved needle, needle breakage and adverse reactions such as subcutaneous hematoma, therefore we will evaluate the safety of acupuncture.

Overall study start date
01/10/2014

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Patients with breast cancer at the age of 25 to 55 years old
2. Neuropsychological evidence of cognitive impairment
3. In the 28 months after chemotherapy according to DSM-IV diagnosis of cognitive impairment
4. According to the MoCA score < 26 points, determining with cognitive dysfunction
5. There is a causal relationship between chemotherapy and cognitive impairment, and except for other diseases
6. The type of traditional Chinese medicine is a disorder of qi and blood
7. At least one field of cognitive dysfunction
8. Diagnosis of dementia standard has not yet arrived
9. Have signed informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100

Key exclusion criteria
1. Because of the depression, thyroid disease, traumatic brain injuries, drug or alcohol poisoning cause cognitive impairment
2. Patients with severe aphasia, depression and mental illness
3. Patients with severe heart, liver, lung, kidney damage caused by cognitive decline and hematopoietic system, endocrine system, severe primary disease
4. Patients can affect the cognitive function of drugs

Date of first enrolment
01/10/2014

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine (TCM)
No.23, Back Road of Gallery
Dong Cheng District
Beijing
China
100010

Sponsor information

Organisation
Beijing Hospital of Traditional Chinese Medicine (TCM)

Sponsor details
No.23, Back Road of Gallery
Dong Cheng District
Beijing
China
100010

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Beijing Hospital of Traditional Chinese Medicine (TCM)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request