

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	☐ Prospectively registered ☐ Protocol
Registration date 25/03/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 25/03/2015	Condition category Cancer	☐ 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

Dr Qing Zhang

Contact details

No.23 Back Road of Gallery

Dong Cheng District

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China

100010

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised single-blinded placebo-controlled study

Study type(s)

Treatment

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(s)

Using the Montreal Cognitive Assessment MoCA to 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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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Dong Cheng District

Beijing
China
100010

Sponsor information

Organisation

Beijing Hospital of Traditional Chinese Medicine (TCM)

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Beijing Hospital of Traditional Chinese Medicine (TCM)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request