

Effect of acupuncture on patients with cancer-related fatigue during chemotherapy

Submission date 26/11/2014	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 24/03/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/03/2015	Condition category Signs and Symptoms	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Adverse reaction is a key factor determining whether cancer patients can receive chemotherapy. It is also one of the main reasons for treatment failure. Fatigue is the most common symptom experienced by patients during chemotherapy. Fatigue is under-reported and often not screened for, partly because of a lack of helpful treatments. Many studies have investigated the benefits and success of acupuncture in easing symptoms for fatigue. Thus, the purpose of this study is to assess the effect of acupuncture on patients with cancer-related fatigue during chemotherapy.

Who can participate?

Patients with breast cancer or lung cancer who have at least two cycles of chemotherapy planned during the study program.

What does the study involve?

Participants are randomly allocated to one of two groups: the intervention group or the control group. Participants in the intervention group will receive acupuncture therapy three times a week for 3 weeks. Participants in the control group will receive shallow needle insertion that does not penetrate below the skin (minimal or superficial needling) at non-acupoints three times a week for 3 weeks. All the participants will complete some questionnaires at the start of the study and at the 3rd day, 7th day, 14th day and 21st day during the chemotherapy to find out about any changes in fatigue level, sleep, appetite and emotion. They will be followed up for a chemotherapy cycle (21 days) to assess long-term effectiveness.

What are the possible benefits and risks of participating?

All participants will receive free acupuncture treatment for nine times and a series of free examinations. The fatigue could be relieved. The results of this study may help to provide evidence that acupuncture is effective for managing cancer-related fatigue during chemotherapy. The risks of taking part are minimal. Acupuncture is a very safe treatment. The acupuncturist has an acupuncture license (Chinese medicine practitioner license) from the Ministry of Health of the People's Republic of China and takes an educational course to ensure that they strictly follow the study method and are familiar with conducting the study. Occasionally acupuncture can make people feel nauseous or faint, or can cause a temporary

increase in pain or a blood clot beneath the skin either during or after treatment. Participants are warned of these potential side-effects before consenting to have acupuncture.

Where is the study run from?

The study is run from three locations:

1. Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, China
2. Beijing ShiJiTan Hospital affiliated to Capital Medical University, China
3. Beijing Friendship Hospital affiliated to Capital Medical University, China

When is the study starting and how long is it expected to run for?

From January 2014 to December 2016.

Who is funding the study?

Beijing Municipal Administration of Hospitals (China).

Who is the main contact?

Dr Xiaomin Wang

wangxiaomin_bhtcm@126.com

Contact information

Type(s)

Scientific

Contact name

Dr Wang Xiao-Min

Contact details

No 23

Back Road of Art Gallery

Dong Cheng District

Beijing

China

100010

+86 (0)10 52176900

wangxiaomin_bhtcm@126.com

Additional identifiers

Protocol serial number

XM201410

Study information

Scientific Title

Acupuncture for prevention and treatment of cancer-related fatigue during chemotherapy: a study protocol for a multicenter, randomized, controlled clinical trial

Study objectives

To assess the therapeutic effect of acupuncture on patients with cancer-related fatigue during chemotherapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Beijing Hospital of Traditional Chinese Medicine Research Ethical Committee, 27/12/2014, ref: 2014BL-067

Primary study design

Interventional

Study design

Multicenter randomized controlled interventional clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cancer-related fatigue

Interventions

The 112 eligible participants are randomly allocated to two different groups:

1. Participants in the intervention group will receive acupuncture therapy three times a week for 3 weeks.
2. Participants in the control group will receive minimal acupuncture therapy (shallow acupuncture at sham points) three times a week for 3 weeks.

All the participants will complete some questionnaires at the start of the study and at the 3rd day, 7th day, 14th day and 21st day during the chemotherapy to find out about any changes in fatigue level, sleep, appetite and emotion. They will be followed up for a chemotherapy cycle (21 days) to assess long-term effectiveness.

Intervention Type

Other

Primary outcome(s)

Piper Fatigue Scale-Chinese Version (PFS-CV), a multidimensional assessment tool for measuring the level of fatigue subjectively for patients with cancer. It will be assessed before chemotherapy, at the 3rd day, 7th day, 14th day and 21st day during the chemotherapy

Key secondary outcome(s)

1. TCM symptoms scale to evaluate TCM syndrome (deficiency of spleen qi and stomach qi)
2. TCM (traditional Chinese medicine) syndrome will be assessed before chemotherapy and at the 3rd day, 7th day, 14th day and 21st day during the chemotherapy

Completion date

31/12/2016

Eligibility

Key inclusion criteria

1. Patients with a definite pathologic diagnosis of breast cancer or lung cancer who had completed chemotherapy and/or radiotherapy at least 3 months, or never received chemotherapy and/or radiotherapy ever before
2. Aged 18-75
3. There are at least two cycles of chemotherapy planned during the study program
4. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
5. Traditional Chinese Medicine (TCM) syndrome is differentiated as deficiency of spleen qi and stomach qi
6. Anticipated survival time is more than 6 months
7. All patients provided written informed consent before enrollment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

All

Key exclusion criteria

1. Complicated with other serious heart, liver, kidney, immune and hematopoietic system diseases
2. Pregnant women or women who are breastfeeding
3. Patients who were on active treatment for anaemia (i.e., EPO or blood transfusions)
4. Patients who were receiving steroids to alleviate fatigue
5. Patients who had been diagnosed with depression, anxiety disorders, mental illness and cognitive disorders
6. Patients who had low platelet count or suffered from a bleeding disorder (e.g., haemophilia)
7. Complicated with sepsis or bacteremia
8. Patients who had lymphoedema at the area of the acupuncture points
9. Patients who are allergic to stainless steel needle or had needle phobia

Date of first enrolment

01/01/2014

Date of final enrolment

31/12/2016

Locations

Countries of recruitment

China

Study participating centre

Beijing Hospital of Traditional Chinese Medicine

No.23, Back Road of Gallery

Beijing

China

100010

Study participating centre

Beijing ShiJiTan Hospital

10 Tieyi Road

Haidian

Beijing

China

Study participating centre

Beijing Friendship Hospital

36 Yong'an Rd

Xicheng

Beijing

China

Sponsor information

Organisation

Beijing Municipal Administration of Hospitals

ROR

<https://ror.org/04baakq55>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Beijing Municipal Administration of Hospitals

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request