

Traditional Chinese medicine (TCM) for cancer-related fatigue in patients with breast cancer

Submission date 27/07/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/08/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/05/2015	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Cancer-related weakness (fatigue) is a symptom frequently experienced by survivors regardless of the type of cancer or its treatment. Evidence of better ways to manage this is scarce. This purpose of this study is to find out the safety and effectiveness of Traditional Chinese Medicine (TCM) for the management of cancer-related weakness.

Who can participate?

Women with definite diagnosis of breast cancer who feel fatigue or tired can participate in this study.

What does the study involve?

Participants are randomly allocated to one of two groups: the intervention group and the control group. Participants in the intervention group will be treated with TCM granules. Participants in the control group will receive placebo (dummy) granules. They will complete some questionnaires at the start of the study and at fortnightly intervals to find out about any changes in fatigue level, sleep and emotion. They will undergo some tests at the start of the study and after treatment in order to find out about the safety. They will be followed up for one month to assess long-term effectiveness.

What are the possible benefits and risks of participating?

All participants will receive free treatment for one month and a series of free examinations. The fatigue could be relieved. The result of this study may help to provide evidence that Traditional Chinese Medicine is safe and effective for managing cancer-related fatigue. Participants have to visit the hospital regularly, which may be inconvenient and disturb their routine. They will have some mild side effects when they start taking TCM granules, such as loss of appetite. That will relieve gradually as they adapt to the smell and taste of TCM.

Where is the study run?

The study is run from three locations in China:

1. Beijing Hospital of Traditional Chinese Medicine
2. Beijing Cancer Hospital
3. People's Hospital of Beijing Daxing District

When is the study starting and how long is it expected to run for?
The study will start in August 2013 and will end in December 2015.

Who is funding the study?
Beijing Municipal Science and Technology Commission, China.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
D131100002213001

Study information

Scientific Title
Traditional Chinese medicine for cancer-related fatigue in patients with breast cancer: a randomized, double-blinded, placebo-controlled trial

Study objectives
The purpose of this study is to determine whether traditional Chinese medicine is effective in managing cancer-related fatigue.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Beijing Hospital of Traditional Chinese Medicine, 22/04/2013, ref: 201338

Study design
Multicentre randomized double-blinded placebo-controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cancer-related fatigue

Interventions

The 118 eligible participants are randomly assigned to two different groups:

1. Intervention group: Chinese medicine granules (15.75g granules per bag, 2 bags per day) twice a day for one month.
2. Control group: placebo granules (15.75g granules per bag, 2 bags per day) twice a day for one month.

The patients receive assessments fortnightly interval and one month after treatment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. TCM symptoms scale is a instrument for detecting states of the TCM Symptoms.
2. Revised Piper Fatigue Scale-Chinese Version(RPFS-CV), a multidimensional assessment tool for measuring the level of fatigue subjectively for patients with cancer.
3. Eastern Cooperative Oncology Group Performance Status (ECOG PS)

These scales and criteria are used by researchers to assess how a patient's disease is progressing, assess how the disease affects the daily life of the patient.

The outcome measures above will be assessed before the treatment, at 2 and 4 weeks during the treatment, the assessments will be repeated at the end of the first month after the treatment.

Key secondary outcome(s)

1. Self-Rating Scale of Sleep (SRSS) is a instrument for detecting states of sleeping.
2. The Hospital Anxiety and Depression Scale (HADS) is an instrument for detecting states of depression and anxiety.

The outcome measures above will be assessed before the treatment, at 2 and 4 weeks during the treatment, the assessments will be repeated at the end of the first month after the treatment.

Completion date

31/12/2015

Eligibility

Key inclusion criteria

1. Women patients having definite pathologic diagnosis of breast cancer in outpatient
2. Patients who had chemotherapy and /or radiotherapy at least 1 month and mastectomy within

5 years

3. Stage I to III breast cancer with no evidence of recurrence and metastasis

4. Eastern Cooperative Oncology Group (ECOG) performance status 0-2

5. Traditional Chinese Medicine (TCM) syndrome is differentiated as liver depression and spleen deficiency

6. Anticipated survival time more than six months

7. Patients having no plan to receive chemoradiotherapy during the study

8. patients who are suffering from at least moderate fatigue by Revised Piper Fatigue Scale-Chinese Version(RPFS-CV)

9. All patients who have provided signed informed consent before enrollment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Patients with serious diseases of heart, liver and kidney, immune and hematopoietic system

2. Children, women who are pregnant

3. Active treatment for anemia with erythropoietin or blood transfusions

4. Patients using steroids to cure cancer-related fatigue

5. Patients having a diagnosis of depression, mental disease and cognitive impairment

6. Patients allergic to Chinese herbal compound

Date of first enrolment

01/08/2013

Date of final enrolment

31/12/2015

Locations

Countries of recruitment

China

Study participating centre

Beijing Hospital of Traditional Chinese Medicine

China

Study participating centre

Beijing Cancer Hospital
China

Study participating centre
People's Hospital of Beijing Daxing District
China

Sponsor information

Organisation
Beijing Municipal Science and Technology Commission (China)

ROR
<https://ror.org/034k14f91>

Funder(s)

Funder type
Government

Funder Name
Beijing Municipal Science and Technology Commission (China)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/04/2015		Yes	No