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

Submission date
27/07/2013

Recruitment status
No longer recruiting

Registration date
14/08/2013

Overall study status
Completed

Last Edited
01/05/2015

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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?
Dr Xiaomin Wang
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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
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

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
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 measure
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.

Secondary outcome measures

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.

Overall study start date
01/08/2013

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

Age group
Adult

Sex
Female

Target number of participants
118

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)

Sponsor details
No.16 Xizhimen South Street
Xi Cheng District
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100035

Sponsor type
Government

ROR
https://ror.org/034k14f91

Funder(s)

Funder type
Government

Funder Name
Beijing Municipal Science and 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

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