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Traditional Chinese medicine for the management of aromatase inhibitor-associated musculoskeletal symptoms

Submission date
24/07/2013

Recruitment status
No longer recruiting

Registration date
14/08/2013

Overall study status
Completed

Last Edited
25/10/2017

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Women with breast cancer treated with a type of drug called aromatase inhibitors (AIs) may experience symptoms affecting muscles and bones that can lead to treatment having to be stopped. It is important to find a safe and effective treatment strategy to manage these symptoms. The purpose of this study is to find out how well traditional Chinese medicine (TCM) works for the management of aromatase inhibitor-associated musculoskeletal symptoms and its safety.

Who can participate?
Women with a history of stage I to III breast cancer who are currently taking a third-generation AI and have ongoing symptoms affecting bones and muscles, which started or worsened after initiation of AI therapy, can participate in the study.

What does the study involve?
Participants are randomly allocated to one of two groups: the treatment group and the control group. Women in the treatment group will receive calcium, vitamin D3 and TCM granules. The control group will be given calcium, vitamin D3 and placebo (dummy) granules. Participants will complete questionnaires at the start of the study and every month after that to find out about changes in pain, movement 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 three months to assess long-term effectiveness.

What are the possible benefits and risks of participating?
All participants will receive free treatment for 3 months and a series of free tests. The symptoms of the bones and muscles could be relieved. The result of this study may help to provide evidence that
traditional Chinese medicine is safe and effective. You have to visit hospital regularly, which may be inconvenient and may disturb your routine. You will have some mild side effects when you start taking TCM granules, such as nausea. That will resolve gradually as you adapt to the smell and taste of TCM.

Where is the study run from?
The study is run from three locations:
1. Beijing Hospital of Traditional Chinese Medicine, China
2. Beijing Cancer Hospital, China
3. Guang' anmen Hospital, China Academy of Chinese Medical Sciences, China

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
elva_pn@163.com

Contact information

Type(s)
Scientific

Contact name
Dr Xiaomin Wang

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

Additional identifiers

Protocol serial number
D131100002213001

Study information

Scientific Title
Randomized, double-blinded, placebo-controlled trial of traditional Chinese Medicine for the management of aromatase inhibitor-associated musculoskeletal symptoms

Study objectives
The purpose of this study is to determine whether traditional Chinese medicine is effective in managing aromatase inhibitor-associated musculoskeletal symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Research Ethical Committee of the Beijing Hospital of Traditional Chinese Medicine, 22/04/2013, ref: 201337

Study design
Multicentre randomised double-blinded placebo-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Aromatase inhibitor-associated musculoskeletal symptoms

Interventions
The 84 eligible participants are randomly allocated to two different groups:
1. Treatment group: Calcium carbonate and vitamin D3 tablets (Ca 600mg+ vitD3 125IU per tablet, 2 tablets per day) twice a day for 3 months, Chinese medicine granules (12.375g granules per bag, 2 bags per day) twice a day for 3 months.
2. Control group: Calcium carbonate and vitamin D3 tablets (Ca 600mg+ vitD3 125IU per tablet, 2 tablets per day) twice a day for 3 months, placebo granules (12.375g granules per bag, 2 bags per day) twice a day for 3 months.
The patients receive assessments every month during the treatment and the third month after the treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. The Brief Pain Inventory-Short Form (BPI-SF) to evaluate general pain
2. Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index to assess joint pain, stiffness, and functional status in the knees.
3. The Modified Score for the Assessment and quantification of Chronic Rheumatoid Affections fo the hands (M-SACRAH) to assess joint pain, stiffness, and functional status in the hands.
The outcome measures above will be assessed before the treatment, at 1 month, 2 and 3 months during the treatment, the assessments will be repeated at the third month after the treatment.

Key secondary outcome(s))
1. The Functional Assessment of Cancer Therapy breast cancer-specific quality of life tool (FACT-B) to evaluate quality of life of patients with breast cancer.
2. TCM symptoms scale to evaluate TCM syndrome (deficiency of liver and kidney, qi and collaterals stagnation).
3. Bone Mineral Density (BMD) to evaluate bone density and bone metabolism objectively
4. Bone Metabolic Markers (calcium, phosphorus, alkaline phosphatase, osteocalcin, calcitonin) to evaluate bone density and bone metabolism objectively
FACT-B and TCM syndrome will be assessed before the treatment, at 1 month, 2 and 3 months

during the treatment, the assessments will be repeated at the third month after the treatment. BMD and bone metabolic markers will be assessed before and after the treatment.

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Stage I-III breast cancer with no evidence of recurrence and metastasis, completed chemotherapy and/or radiotherapy
2. Use of a third-generation aromatase inhibitor (AI) and self-report ongoing musculoskeletal symptoms after initiation of aromatase inhibitor (AI) therapy
3. A baseline worst pain score over the past week on the Brief Pain Inventory-Short Form (BPI-SF) of ≥3 points on a scale of 0 to 10
4. Traditional Chinese Medicine (TCM) syndrome is differentiated as deficiency of liver and kidney, qi and collaterals stagnation
5. Anticipated survival time is more than six months
6. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
7. All patients provided written informed consent before enrollment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Patients with endocrine and any other diseases influencing bone metabolism (hyperthyroidism, hypothyroidism, diabetes, chusing syndrome, chronic liver disease, nephropathy, myeloma, bone tumor, bone metastasis)
2. Use of the agents influencing bone metabolism (glucocorticoid, thyroid hormone, heparin, anticonvulsant, diuretic, bisphosphonates) except calcium within the past three months
3. Contraindication in calcium agent and vitamin D
4. Diagnosis of primary osteoarticular diseases
5. Complicated with other primary tumors and serious heart, liver, kidney and hematopoietic system diseases
6. Pregnancy, mental illness and cognitive handicap

Date of first enrolment
01/08/2013

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
China

Study participating centre
No.23, Back Road of Gallery, Dong Cheng District, Beijing, China
Beijing
China
100010

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
The datasets and analysis will be included in the results publication. For any questions, contact elva_pn@163.com

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2018		Yes	No

Protocol article	protocol	15/05/2014	Yes	No