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Dang-Gui-Liu-Huang-Tang, a Chinese herbal medicine formula, may relieve breast cancer patients' side effects under adjuvant chemotherapy: a randomized placebo-controlled trial.

Submission date
05/08/2023

Recruitment status
No longer recruiting

Registration date
24/10/2023

Overall study status
Completed

Last Edited
24/10/2023

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Breast cancer is one of the most common malignancies among female patients. Side effects may concern patients, and relieving side effects becomes one of the most important clinical issues during the treatment course. Therefore, relieving side effects without delaying chemotherapy becomes a critical issue.

Who can participate?
Female breast cancer patients aged between 18 and 65 years old with prior surgery and current chemotherapy-only treatment

What does the study involve?
After adequate randomization and allocation, Dang-Gui-Liu-Huang-Tang is given for treatment group subjects, while a placebo with similar smell and color is given for control group subjects.

The severity of side effects is used as the primary outcome, and neutrophil function is assessed as the secondary outcome.

What are the possible benefits and risks of participating?
Dang-Gui-Liu-Huang-Tang may relieve discomforts caused by chemotherapy used in treating breast cancer, such as fatigue and vomiting.

The possible side effects, such as nausea, vomiting, and fatigue, are assessed by CTCAE 4.0 classifications, and the comparisons between control and treatment groups will be assessed.

Where is the study run from?
The Chang Gung Memorial Hospital, Linkou, and Taoyuan branches (China)

When is the study starting and how long is it expected to run for?
March 2008 to November 2011

Who is funding the study?
Chang Gung Medical Foundation (CMRPG370671) (China)

Who is the main contact?
Dr Hsing-Yu Chen, 8705016@cgmh.org.tw

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CMRPG370671, 200800208B0

Study information

Scientific Title
Dang-Gui-Liu-Huang-Tang for breast cancer patients' side effects

Study objectives
Dang-Gui-Liu-Huang-Tang could relieve side effects along with chemotherapy among breast cancer patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/04/2008, Chang Gung Medical Foundation Institutional Review Board, FAO Shih-Hua Huang (No.5, Fuxing St., Gueishan Dist., 33305, Taiwan; +886-3-319-6200#3712; shihhua@cgmh.org.tw), ref: 97/1479C

Study design
Randomized placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life, Treatment, Efficacy

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Relief of side effects of chemotherapy among breast cancer patients

Interventions
Dang-Gui-Liu-Huang-Tang is a classic Traditional Chinese Medicine (TCM) formula commonly made for menopausal syndrome by modulating patients' immunity and endocrine imbalance. Since severe menopausal syndrome and discomforts following treatment for breast cancer could be seen among breast cancer patients, Dang-Gui-Liu-Huang-Tang is therefore used for breast cancer patients in clinical practice for symptom relief. For this reason, this study is being conducted to examine the effect of Dang-Gui-Liu-Huang-Tang as an additional therapy for breast cancer. Dang-Gui-Liu-Huang-Tang is given three times a day, 4 grams each time, along with chemotherapy for breast cancer. For example, cyclophosphamide-fluorouracil-methotrexate (CMF) chemotherapy will be given every three weeks, for a total of 9 rounds of CMF treatment; while cyclophosphamide, epirubicin, fluorouracil (CEF) will be given every three weeks, for a total of 6 rounds of CEF treatment. On the other hand, placebo medicine with similar color and smell is given at the same frequency and quantity. All enrolled patients are assigned to treatment using a number generated by a random sequence and equally distributed to two groups in 1:1 ratio. Principal investigator (PI) and co-PIs are responsible for patient evaluation; research assistants have expertise in collecting patients' information and lab data. Additionally, TCM pharmacists are responsible for delivering trial medicine to enrolled subjects. All medicines are delivered face-to-face by TCM pharmacists after recognizing the assigned number of each subject. The entire trial will be conducted in the Chang-Gung Memorial Hospital, Linkou branch, Taoyuan, Taiwan.

Intervention Type
Drug

Pharmaceutical study type(s)
Not Applicable

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Dang-Gui-Liu-Huang-Tang

Primary outcome measure

Side effects measured using the MD Anderson Symptom Inventory (MDASI), the Functional Assessment of Cancer Therapy - Breast (FACT-B) questionnaire and CTCAE 4.0 grading from day 0 and every three weeks

Secondary outcome measures
Neutrophil function measured using a neutrophil phagocytosis assay at day 0 and every 3 weeks

Overall study start date
01/03/2008

Completion date
30/11/2011

Eligibility

Key inclusion criteria
1. Breast cancer patient receives adjuvant chemotherapy
2. Age ranges from 18 to 65 years
3. Not receiving Chinese herbal medicine within one month before enrollment
4. Adequate bone marrow reserve: platelets100*10^9/L, absolute neutrophil count (ANC) 1. 5*10^9/L, hemoglobin9.0g/d, adequate liver function tests: serum bilirubin <1.5mg/dL, ALT and AST <2.5*ULN, adequate renal function: creatinine 2 mg/dL or estimated creatinine clearance >40mL/min, calcium1.2*ULN
5. Diagnosed as the Traditional Chinese medicine (TCM) pattern "Qi and blood deficiency" by a TCM doctor
6. Willing to sign the informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Female

Target number of participants
118

Total final enrolment
112

Key exclusion criteria

1. Patients receive concurrent therapies other than chemotherapy, such as radiotherapy or hormone therapy, or are unsuitable for chemotherapy
2. With severe underlying diseases, mental illness, and infectious diseases
3. Women with breastfeeding or pregnancy
4. Subjects with cardiovascular diseases but without adequate treatments or with a history of myocardial infarction within recent six months
5. Not diagnosed as Traditional Chinese medicine (TCM) pattern "Qi and blood deficiency"
6. Chemotherapy is stopped and will not be continued within one month
7. Any intolerant adverse events during the study period
8. Subjects with liver or renal function deteriorating, and the discontinuation of the clinical trial is requested by investigators

Date of first enrolment
01/11/2008

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
Taiwan

Study participating centre
Chang Gung Memorial Hospital, Linkou branch
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Study participating centre
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Sponsor type
Hospital/treatment centre

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Funder(s)

Funder type
Research organisation

Funder Name
Chang Gung Medical Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Taiwan

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets used in this current study will be available under adequate request and approval from the IRB committee.

IPD sharing plan summary

Available on request