INPLASY PROTOCOL

Corresponding author:
Zhenming Xie

1766309244@qq.com

Author Affiliation:
Evidence-based Medicine Research Center, Guizhou University of Traditional Chinese Medicine.

Review Stage at time of this submission: The review has not yet started.

Conflicts of interest: None declared.

Efficacy and safety of Chaihu Shugan Powder plus or minus combined with chemotherapy to treat breast cancer

Xie, ZM[1]; Zhu, XM[2]; Liu, J[3]; Chen, J[4]; Ke, LZ[5]; Tian, SX[6]; Luo, L[7]; Yang, Z[8]; Tang, DX[9].

Review question / Objective: Is Chaihu Shugan Powder plus or minus combined with chemotherapy effective and safe in adjuvant treatment of breast cancer?
Condition being studied: Breast cancer (BRCA).
Information sources: Literature databases: PubMed, EMBASE, the Cochrane Library , China Biomedical LiteratureDatabase, Chinese National Knowledge Infrastructure, Wanfang Data, and Chongqing Weipu Chinese Science(VIP) Trial registry: Clinicaltrials.gov, and Chinese Clinical Trial Registry. Source of grey literature: reference lists of relevant reviews.

INTRODUCTION

Review question / Objective: Is Chaihu Shugan Powder plus or minus combined with chemotherapy effective and safe in adjuvant treatment of breast cancer?

Rationale: Breast cancer(BRCA) ranks the first among female malignancies. At present, there are about 1.7 million new cases of breast cancer in the world every year, more than 52% of the cases and 62% of the deaths of breast cancer patients occur in some countries of lower income and middle class respectively, posing a

serious threat to women's health.Studies have shown that Chaihu Shugan Powder has the effect of phytoestrogens, which can effectively antagonize human estrogen, reduce the level of estrogen in the body, and achieve the effect of preventing and treating breast cancer. Pharmacologically, Chaihu Shugan Powder can induce apoptosis of breast cancer MCF-7 cells by inhibiting the levels of Bcl-2 protein and VEGF factor, it can also increase and down-regulate the expression level of protein kinase C in human TH cells and the differentiation signal of TH cells, thus enhancing the immune system of the body and alleviating bone marrow suppression. Therefore, this study intends to conduct a meta-analysis of randomized controlled trials of Chaihu Shugan Powder as the basic prescription combined with chemotherapy in breast cancer patients to provide evidence.

Condition being studied: Breast cancer (BRCA).

METHODS

Search strategy: In this study, Chinese and English studies of public publications were retrieved.4 Chinese databases cover China Knowledge Network Infrastructure(CNKI) database, WanFang Data Knowledge Service Platform, Chongqing Weipu Chinese Science(VIP) and China Biomedical Literature Database(CBM), 3 English database include PubMed, the Cochrane Library and Embase. The time range of the search will be from the database to July 31, 2021.Search strategy in PubMed is: (Breast Neoplasm[mh] OR Neoplasm,Breast[tw] OR Breast Tumor[tw] OR Breast Tumors [tw] OR Tumor, Breast[tw] OR Tumors, Breast[tw] OR Neoplasms, Breast[tw] Breast Cancer[tw] OR Cancer,Breast[tw] OR Cancer,Mammary[tw] OR Mammary Cancer [tw] OR Cancers, Mammary[tw] OR Mammary Cancers [tw] OR Malignant Neoplasm of Breast[tw] OR Breast Malignant Neoplasm[tw] OR Breast Malignant Neoplasms[tw] OR Malignant Tumor of Breast[tw] OR Breast Malignant Tumor [tw] OR Breast Malignant Tumors [tw] OR Cancer of Breast [tw] OR Cancer of the Breast [tw] OR Mammary Carcinoma[tw])AND (Chaihu Shugan Powder[tw] OR Chaihu Shugan Powder plus[tw] OR Chaihu Shugan Powder minus[tw] OR Chaihu Shugan Powder plus or minus[tw] OR Soothing liver and strengthen spleen[tw] OR Soothing liver[tw] OR) AND (Therapy, Drug[tw] OR Chemotherapy[tw] OR Chemotherapies [tw]) NOT(animals[mh] NOT humans[mh]).

Participant or population: Patients with BRCA.

Intervention: Chaihu Shugan Powder plus or minus prescription combined with chemotherapy.

Comparator: The same chemotherapy.

Study designs to be included: Randomized controlled trials (RCTs).

Eligibility criteria: Inclusion criteria: patients diagnosed with breast cancer by pathology or cytology were treated with chemotherapy. Exclusion criteria: We will exclude studies enrolling non-diabetic patients with breast cancer.

Information sources: Literature databases: PubMed, EMBASE, the Cochrane Library , China Biomedical LiteratureDatabase, Chinese National Knowledge Infrastructure, Wanfang Data, and Chongqing Weipu Chinese Science(VIP) Trial registry: Clinicaltrials.gov, and Chinese Clinical Trial Registry. Source of grey literature: reference lists of relevant reviews.

Main outcome(s): Efficacy, Auality of life and Median survival time.

Additional outcome(s): 5-year survival rate, symptom remission rate, KPS scores, bone marrow suppression, gastrointestinal reaction.

Data management: Two investigators (XZM and ZXM) will extract relevant data independently with the standardized sheet recommended by the Cochrane Handbook

of Systematic Reviews of Interventions. The data of those qualified articles will be export to Microsoft Excel, which includes the first author, published year, number of cases, country, diagnosis, treatment, intervention time and outcome indicators. For articles with incomplete or uncertain data, the authors will be contacted for complete data whenever possible. If there is any dispute in the data extraction process, it will be submitted to a third researcher (LJ) for processing.

Quality assessment / Risk of bias analysis: The Cochrane collaboration's tool, an established and reliable tool for assessing the risk of bias, will be used in studies evaluate the risk of bias for each study by two independent reviewers (XZM and ZXM). [17] In this tool, the risk of bias of a trial is evaluated through 7 items, include random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data(attrition bias), selective reporting (reporting bias), other bias.The assessment will be classified as "Low risk," "High risk," or"Unclear risk." Disagreements between the 2 reviewers will be resolved by discussion of all reviewers.

Strategy of data synthesis: RevMan 5.3 software was used for statistical analysis. For dichotomous variables, the odds ratio(OR) will be applied to analyze. For continuous variables, a mean difference (MD) or a standard mean difference (SMD) will be used for analysis. The confidence intervals (CI) for both dichotomous and continuous variables will be set to 95%.

Subgroup analysis: Subgroup analysis was performed based on patients' quality of life: social functioning vs. emotional functioning vs. physiological functioning.

Sensitivity analysis: We will perform the following two sensitivity analyses: 1) excluding studies with high risk of bias; 2) using fixed effects model in meta-analyses.

Language: No restrictions.

Country(ies) involved: China.

Dissemination plans: We aim to publish the results of this systematic review in a peer-reviewed journal.

Contributions of each author:
Author 1 - Zhenming Xie.
Email: 1766309244@qq.com
Author 2 - Xianming Zhu.
Email: 936108232@qq.com
Author 3 - Jie Liu.
Email: 1515987494@qq.com
Author 4 - Jie Chen.
Email: 1206691289@qq.com
Author 5 - Longzhu Ke.
Email: 2586242770@qq.com
Author 6 - Shengxia Tian.
Email: 3281975425@qq.com
Author 7 - Li Luo.
Email: 485135193@qq.com
Author 8 - Zhu Yang.
Email: 1602412711@qq.com
Author 9 - Dongxin Tang.
Email: tangdongxin@sina.com