

Therapeutic effect of upper limb lymphedema after radical operation of mastocarcinoma with Wen Tong Xiao Zhong Wai Fu Fangh for external wet cover

Submission date 09/09/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 25/10/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 08/12/2014	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

We are carrying out a study to find out the effect of Wen Tong Xiao Zhong Wai Fu Fang in relieving the symptoms of upper limb lymphedema (fluid accumulation) after a radical operation for mastocarcinoma (breast cancer). We want to see whether it is effective to moisten and lay Wen Tong Xiao Zhong Wai Fu Fang on the swollen upper limb.

Who can participate?

The study aims to recruit adult men and women who have had a radical operation for mastocarcinoma, whose swollen limb is colder than the normal one.

What does the study involve?

Participants will be invited to have Wen Tong Xiao Zhong Wai Fu Fang or placebo (dummy) pasted on the swollen upper limb from 9am to 5pm everyday for 14 consecutive days. All participants will receive functional exercises during the treatment. Researchers will measure the upper arm circumference to see how well it has worked. At the end of the study, this will be compared amongst different patients to find out the effect of Wen Tong Xiao Zhong Wai Fu Fang.

What are the possible benefits and risks of participating?

The results of the study may provide a new way to relieve the symptoms of lymphedema after a radical operation for mastocarcinoma. The main risk of this study is unknown allergy because Wen Tong Xiao Zhong Wai Fu Fang includes many Chinese medicinal herbs which are potential allergens. If this occurs, the volunteer can quit the study.

Where is the study run from?

The study is run from the following hospitals in China:

1. Dongfang Hospital affiliated to Beijing University of Chinese Medicine
2. Chinese PLA General Hospital

3. Peking University People's Hospital
4. Cancer Institute and Hospital Chinese Academy of Medical Sciences (CAMS)

When is study starting and how long is it expected to run for?

The study started in mid-2013. Participants will be enrolled on the study for a period of one and a half years.

Who is funding the study?

Funding has been provided by Beijing Municipal Science and Technology Commission, China.

Who is the main contact?

Dr Kaiwen Hu

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Contact information

Type(s)

Scientific

Contact name

Dr Kaiwen Hu

Contact details

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100078

Additional identifiers

Protocol serial number

D131100002213003

Study information

Scientific Title

Therapeutic effect of upper limb lymphedema after radical operation of mastocarcinoma with Wen Tong Xiao Zhong Wai Fu Fangh for external wet cover: a double-blind randomised parallel group multi-site trial

Acronym

WTXZWFF

Study objectives

Wen Tong Xiao Zhong Wai Fu Fang is a kind of traditional Chinese medicine for external use. It might be effective to moisten and lay "Wen Tong Xiao Zhong Wai Fu Fang" on upper limb lymphedema after radical operation of mastocarcinoma

Ethics approval required

Old ethics approval format

Ethics approval(s)

Clinical Research Ethics Committee Office of Dongfang Hospital Affiliated to Beijing University of Chinese Medicine

Primary study design

Interventional

Study design

Double-blinded randomised parallel-group multi-site trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Upper limb lymphedema after radical operation of mastocarcinoma

Interventions

The study will involve 96 volunteers recruited at four trial centres. Participation will be for a period of one year and six months. 96 volunteers are divided averagely into two groups. Patients in Group 1. will be treated with gWen Tong Xiao Zhong Wai Fu Fangh as well as functional exercise.

Patients in Group 2. will be treated with the placebo of gWen Tong Xiao Zhong Wai Fu Fangh and functional exercise.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Clinical efficiency: It is effective when the average upperarm circumference of the swollen limb decrease by 2cm or more.

Key secondary outcome(s)

Disability of Arm- Shoulder- Hand (DASH)

Completion date

31/12/2014

Eligibility**Key inclusion criteria**

1. Aged over 18 years
2. Patients suffering radical operation of mastocarcinoma
3. Patients in Stage 1 and 2 based on the 4 stages of upper limb lymphedema after radical operation of mastocarcinoma sorted by American Physical Therapy Association

4. Local identification of cold pattern, which means the swollen limb feels colder than the normal one and this kind of patients prefers warm than cold, likes hot food and hates cold ones

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Patients with other diseases, such as phlebitis, lymphangitis or thrombotic diseases, which may cause upper limb edema
2. Patients suffering lymphatic metastasis
3. Pregnant women and nursing mothers
4. Patients having rash, papules, erythema, herpes, exfoliative dermatitis or ulcerative dermatitis in the affected limb's skin
5. Patients received radiation therapy

Date of first enrolment

01/07/2013

Date of final enrolment

31/12/2014

Locations

Countries of recruitment

China

Study participating centre

Dongfang Hospital

No. 6, District 1

Fangxingyuan

Beijing

China

100078

Study participating centre

Chinese PLA General Hospital

28 Fuxing Road

Beijing

China

100853

Study participating centre**Peking University People's Hospital**

11 Xizhimen S St

Xicheng

Beijing

China

Study participating centre**Cancer Institute and Hospital Chinese Academy of Medical Sciences (CAMS)**

No.17 Panjiayuananli

Chaoyang District

P.O. Box 2258

Beijing

China

100021

Sponsor information

Organisation

Beijing Municipal Science and Technology Commission (China)

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

Beijing Qihuang Drug Clinical Research Center (China)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration