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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Fangis 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

Study design
Double-blinded randomised parallel-group multi-site trial

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
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 measure

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

Secondary outcome measures
Disability of Arm- Shoulder- Hand (DASH)

Overall study start date
01/07/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
96

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 Panjiayuannanli
Chaoyang District
P.O. Box 2258
Beijing
China
100021

Sponsor information

Organisation
Beijing Municipal Science and Technology Commission (China)

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Sponsor type
Government

ROR
https://ror.org/034k14f91

Funder(s)

Funder type
Research organisation

Funder Name
Beijing Qihuang Drug Clinical Research Center (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