

# The clinical study of pasting "Wei Tan Wai Fu Fang" on acupuncture point to treat patients suffering postoperative gastroparesis of digestive cancer

<b>Submission date</b> 28/08/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/10/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/12/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

We are carrying out a study to find out the effect of "Wei Tan Wai Fu Fang" on the symptoms of postoperative gastroparesis (abnormal functioning of the stomach after surgery) in digestive cancer. We want to see whether it is effective to paste "Wei Tan Wai Fu Fang" on acupuncture point when treating postoperative gastroparesis of digestive cancer.

### Who can participate?

The study aims to recruit adult men and women suffering from postoperative gastroparesis of digestive cancer whose local identification of abdomen is cold pattern ,which means this kind of patient prefers heat to cold ,likes hot food and hates cold ones.

### What does the study involve?

Over a period of one and a half years participants will be invited to have Wei Tan Wai Fu Fang or placebo (dummy) on two acupuncture points every morning . This can be had along with the routine treatment . At the end of the study , we will find out the effects of having Wei Tan Wai Fu Fang on acupuncture points when treating postoperative gastroparesis of digestive cancer.

### What are the possible benefits and risks of participating?

The results of the study are likely to find out a new way to treat the symptoms of postoperative gastroparesis of digestive cancer. The main risk of this study is unknown allergy because Wei Tan 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 recruitment started in mid-2013. Participants will be enrolled in the study for a year and a half.

Who is funding the study?

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 Hu Kaiwen

### Contact details

No. 6, District 1, Fangxingyuan, Fangzhuang, Fengtai District, Beijing, P.R. China

Beijing

China

100078

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

D131100002213003

## Study information

### Scientific Title

The clinical study of pasting "Wei Tan Wai Fu Fang" on acupuncture point to treat patients suffering postoperative gastroparesis of digestive cancer: a double-blind randomised parallel group multi-site trial

### Acronym

WTWFF

**Study objectives**

It might be effective to paste "Wei Tan Wai Fu Fang" on acupuncture point when treating postoperative gastroparesis of digestive cancer.

**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-blind 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**

Postoperative gastroparesis of digestive cancer

**Interventions**

This is a double-blind randomised parallel group multi-site trial. 120 volunteers are divided into two groups by a certain people who won't participate in the clinical observation so as to ensure the double-blind observation.

Patients in Group 1 will be treated with Wei Tan Wai Fu Fang as well as conventional therapy (parenteral nutrition, gastrointestinal decompression, prokinetic drugs).

Patients in Group 2. will be treated with the placebo of Wei Tan Wai Fu Fang and conventional therapy.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Clinical efficiency: It is effective when a patient restores motility in two weeks or he is able to take in nutrients by himself after unplugging the nasogastric tube. It is measured by the Gastroparesis Cardinal Symptom Index.

### **Secondary outcome measures**

1. Gastroparesis symptom score
2. The amount of stomach drainage or vomiting

Outcomes will be recorded on the 1st, 3rd, 5th, 7th and 14th day of the treatment.

### **Overall study start date**

01/07/2013

### **Completion date**

31/12/2014

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 years or older
2. Patients suffering postoperative gastroparesis of digestive cancer
3. Local identification is cold pattern. This means that, this kind of patients prefer warm to cold, likes hot food and hates cold one)

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

120

### **Total final enrolment**

128

### **Key exclusion criteria**

1. Gastroscope or gastrointestinal contrast detection indicates that the patient is suffering mechanical intestinal obstruction
2. Patients with other diseases such as diabetes or scleroderma ,which may cause gastroparesis
3. Patients taking drugs like morphine and atropine which affect the function of gastric smooth muscle
4. Patients having rash, papules, erythema, herpes, exfoliative dermatitis or ulcerative dermatitis in the abdominal skin

**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

Fangzhuang

Fengtai District

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

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**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 University of Chinese Medicine (China)

## Sponsor details

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11 N. 3rd Ring Rd E  
Chaoyang  
Beijing  
China  
100078

## Sponsor type

University/education

## ROR

<https://ror.org/05damtm70>

# Funder(s)

## Funder type

Government

## Funder Name

Beijing Municipal Science and Technology Commission (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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	23/12/2017	17/12/2020	Yes	No