

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

Submission date 28/08/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 25/10/2013	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/12/2020	Condition category Cancer	☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Double-blind randomised parallel-group multi-site trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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 gastic 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)

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

Funder(s)

Funder type
Government

Funder Name

Beijing Municipal Science and Technology Commission (China)

Results and Publications

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?
Results article	results	23/12/2017	17/12/2020	Yes	No