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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

Registration date
25/10/2013

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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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 wont 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 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
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100021

Sponsor information

Organisation
Beijing University of Chinese Medicine (China)

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