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The effect of acupuncture in the prevention and treatment of chemotherapy-induced nausea and vomiting in patients with advanced cancer

Submission date
27/11/2014

Recruitment status
No longer recruiting

Registration date
28/02/2015

Overall study status
Completed

Last Edited
06/03/2024

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Nausea and vomiting are the most common symptoms experienced by patients with cancer after chemotherapy. Some patients in chemotherapy still have the symptoms even with common use of antiemetic (anti-vomiting) drugs. The aim of this study is to assess the effects and safety of acupuncture for chemotherapy-induced nausea and vomiting in patients with advanced cancer.

Who can participate?
Patients aged 18-75 with lung cancer, breast cancer or gynecological cancer

What does the study involve?
Participants are randomly allocated to one of two groups: the intervention group or the control group. Participants in the intervention group receive acupuncture therapy 6 times in 5 days. Participants in the control group receive minimal acupuncture therapy 6 times in 5 days. They complete questionnaires at the start of the study and during the study to find out about any changes in the severity of nausea and vomiting, sleep, appetite and emotion. They are followed up for 3 weeks to assess long-term effectiveness.

What are the possible benefits and risks of participating?
All participants receive free treatment for 5 days and a series of free examinations. The symptoms of nausea and vomiting could be relieved. The results of this study may help to provide evidence that acupuncture is effective for managing chemotherapy-induced nausea and vomiting. The risks of taking part are minimal. Acupuncture is a very safe treatment when given by properly trained clinicians. Occasionally acupuncture can make people feel nauseous or faint or experience a temporary increase in pain either during or after treatment. Participants are warned of these potential side-effects before consenting to have acupuncture.

Where is the study run from?
1. Beijing Hospital of Traditional Chinese Medicine (China)
2. Beijing ShijItan Hospital (China)
3. Beijing Friendship Hospital, Capital Medical University (China)

When is the study starting and how long is it expected to run for?
January 2014 to December 2016

Who is funding the study?
Beijing Municipal Administration of Hospitals (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02369107

Protocol serial number
XM201410

Study information

Scientific Title
A multi-center, randomized controlled clinical trial: the effect of acupuncture in the prevention and treatment of chemotherapy-induced nausea and vomiting in patients with advanced cancer

Study objectives
To assess the therapeutic effects and safety of acupuncture for chemotherapy-induced nausea and vomiting in patients with advanced cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Beijing Hospital of Traditional Chinese Medicine Research Ethical Committee, 27/11/2014; ref: 2014BL-067

Study design
Multi-center randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chemotherapy-induced nausea and vomiting

Interventions
The 136 eligible participants are randomly allocated to two different groups:
1. Participants in the intervention group will receive acupuncture therapy 1 hour prior to chemotherapy administration, 6 hours after chemotherapy administration, and once acupuncture therapy on the following day 2 ,3, 4, 5. The stimulation points are RN12, LR13 (bilaterally), RN6, ST25 (bilaterally), PC6 (bilaterally). They will receive Ondansetron Intravenously twice a day during the chemotherapy administration period.
2. Participants in the control group will receive minimal acupuncture therapy at the same time as the intervention group. The stimulation points do not belong to traditional Chinese medicine. They will receive Ondansetron intravenously twice a day during the chemotherapy administration period.

All the patients will complete some questionnaires at the start of the study and at day 1, 2, 3, 7 (±1), 10(±1), 14(±1), 21(±1) intervals to find out about any changes in the severity of nausea and vomiting, sleep, appetite and emotion. They will be followed up for 3 weeks to assess long-term effectiveness.

Intervention Type
Other

Primary outcome(s)
The Common Terminology Criteria for Adverse Events (CTCAE), formerly called the Common Toxicity Criteria (CTC or NCI-CTC), are a set of criteria for the standardized classification of adverse effects of drugs used in cancer therapy. The CTCAE system is a product of the US National Cancer Institute (NCI). It includes the standard to assess nausea and vomiting. It will be assessed at baseline, day 1, day 2, day 3, day 7(±1)day 10(±1), day 14(±1), day 21(±1). Patients have a daily questionnaire about nausea and vomiting during chemotherapy to record their feelings.

Key secondary outcome(s))
1. TCM symptoms scale to evaluate TCM syndrome
2. ECOG score scale to evaluate physical condition of patients
3. HADS: a questionnaire to access the anxiety levels of patients
4. Brief nutritional evaluation
These measures will be assessed at baseline, day 3, day 7(±1), day 14(±1), day 21(±1). Patients will be assessed with questionaire by doctors.

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Patients with definite pathological diagnosis of lung cancer, breast cancer, and gynecological cancer
2. Aged 18-75
3. Patients will receive chemotherapy treatment including cisplatin, anthracycline or taxane during the study period
4. ECOG score is between 0 and 2
5. The patients are diagnosed with insufficiency of spleen-qi and stomach-qi, reverse ascending of Stomach-Qi in traditional Chinese medicine theory
6. The expected lifetime of the patient is longer than 6 months
7. Patients willing to participate in the study and sign the consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Patients have serious disease in cardiovascular system, liver system, kidney system, immune system and hemopoietic system
2. Pregnant and lactating women
3. Patients have intractable vomiting caused by malignant brain metastases, intracranial hypertension, digestive tract obstruction, severe liver or renal dysfunction, brain tumors, cerebrovascular disease, or other reasons
4. Patients with coagulopathy, thrombocytopenia, or suffering from bleeding disorders
5. Patients have been definitely diagnosed with depression, anxiety disorders and psychosis
6. Patients with sepsis or bacteremia
7. Patients have lymphedema in acupuncture stimulation area
8. Patients who are afraid of acupuncture stimulation or allergic to stainless steel needles

Date of first enrolment
10/12/2014

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University
No.23, Back Road of Gallery
Beijing
China
100010

Study participating centre
Beijing ShijItan Hospital
10 Tieyi Road
Haidian
Beijing
China
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Study participating centre
Beijing Friendship Hospital
36 Yong'an Road
Xicheng
Beijing
China
-

Sponsor information

Organisation
Beijing Municipal Administration of Hospitals

ROR
https://ror.org/04baakq55

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Beijing Municipal Administration of Hospitals

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/06/2020	06/03/2024	Yes	No
Protocol article	protocol	20/04/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes