Abstract

Background and aims

Functional dyspepsia (FD) is a long-term condition of the digestive system, that causes discomfort in the upper belly, near the ribs. Although FD is not a life-threatening disease, it has considerable impact on quality of life. There are various available drug treatments for FD which neutralize stomach acid or stop the stomach from producing so much, but many FD patients turn to complementary and alternative therapies as often medications do not provide enough relief. Acupuncture is a popular alternative therapy, derived from ancient Chinese medicine. Although it has been frequently used to treat symptoms of FD, evidence of its effectiveness is lacking. The Rome III consensus subdivided FD into two subgroups: postprandial distress syndrome (an unpleasant feeling of fullness after eating) and epigastric pain syndrome (upper abdominal pain and burning). However, few studies have been conducted to examine the treatment responses of different FD subgroups. The aim of this study is to assess the efficacy of acupuncture in the treatment of postprandial distress syndrome (PDS) patients.

Who can participate?

Male and female patients aged 18-65 diagnosed with PDS.

What does the study involve?

Patients are randomly allocated to one of two groups: a verum acupuncture group or a minimal acupuncture group. The verum acupuncture sessions involve placing needles in specific points on the body, which are stimulated by hand for at least 30 seconds to achieve the typical acupuncture sensation. The minimal acupuncture sessions involve the placement of needles in non-acupoints (places not intended to cause an effect). Both verum acupuncture and minimal acupuncture treatments consist of 12 sessions of 20 minutes duration over 4 weeks (three sessions per week). Participants in both groups are followed up 4, 8 and 16 weeks after first acupuncture.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their symptoms and general quality of life. The risks of receiving acupuncture are minimal. Acupuncture is a relatively safe treatment when given by properly trained clinicians. Occasionally, acupuncture can make people feel nauseous or faint. Participants are warned of these potential side-effects before receiving acupuncture.

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

When is the study starting and how long is it expected to run for?
March 2016 to January 2017

Who is funding the study?
Beijing Municipal Science & Technology Commission (China)

Who is the main contact?
Dr Liu Cun-Zhi

Trial website
Contact information
Type
Scientific
Primary contact
Mr Cun-Zhi Liu
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Additional identifiers

**EudraCT number**
ClinicalTrials.gov number
Protocol/serial number
Z161100000516007

Study information

**Scientific title**
Acupuncture for postprandial distress syndrome (APDS): a pilot randomized controlled trial

**Acronym**
APDS

**Study hypothesis**
The efficacy of verum acupuncture on postprandial distress syndrome (PDS) is superior to minimal acupuncture.

**Ethics approval**
Research Ethical Committee of Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, 14/03/2016, ref: 2016BL-011-01

**Study design**
Two-arm multi-centre randomized controlled pilot trial

**Primary study design**
Interventional

**Secondary study design**
Randomised controlled trial

**Trial setting**
Hospitals

**Trial type**
Treatment

**Patient information sheet**
No specific participant information sheet available, please use the contact details below to request a further information.

**Condition**
Postprandial distress syndrome (PDS)
Intervention
Participants will be randomly assigned to verum acupuncture at acupoints or minimal acupuncture at non-acupoints in a 1:1 ratio.

Verum acupuncture group: Participants in the verum acupuncture group will receive a standardized 20-minute acupuncture session needling at selected points: Baihui(DU20), zhongwan(RN12), Tianshu(ST25), Qihai(RN6), Neiguan(PC6), Danzhong(RN17), Zusani(ST36), Gongsun(SP4). Needles will be stimulated manually at least 30 seconds to achieve the typical acupuncture sensation (deqi). Treatments consist of 12 sessions of 20 minutes duration over 4 weeks (three sessions per week).

Minimal acupuncture group: Participants in the minimal acupuncture group will receive 20-minute acupuncture at non-acupoints. Needles will be placed at non-acupoints with a superficial puncture (2 mm in depth) to avoid de qi and manual stimulation. The location of non-acupoints as following:
1. In the middle of Jiaosun(SJ20) and Shuaigu(GB8) points
2. 2.0 cun above the anterior superior iliac spine
3. 2.0 cun below the umbilicus, and 1.0 cun lateral to the anterior midline
4. In the middle of the medial epicondyle of the humerus and the styloid process of ulna
5. 3.0 cun below Yanglingquan(GB34), between the gallbladder and bladder meridian
6. In the middle of Qiuxu(GB40) and Jiexi(ST41) points
Treatments consist of 12 sessions of 20 minutes duration over 4 weeks (three sessions per week).

The use of other treatments related to PDS will not be allowed for participants in either group. The study will include 4 weeks treatment and 12 weeks follow-up.

Intervention type
Phase
Drug names
Primary outcome measures
Overall treatment effect (OTE) is measured using patient interviews using a Likert scale at baseline, once a week for the four week treatment period and then at 4, 8 and 16 weeks after first acupuncture.

**Secondary outcome measures**

1. Symptoms and global assessment of PDS patients are measured using a four-item questionnaire-asymptomatic (0 point), mild (1 point), moderate (2 points) or severe (3 points)-including eight symptoms: postprandial distension, early satiety, epigastric pain, epigastric burning, upper abdominal bloating, nausea. Assessment will be conducted at baseline, twice a week in treatment period and 8, 16 weeks after first acupuncture.

2. Quality of life is evaluated using the 25-item Nepean Dyspepsia Index (NDI) at baseline, 4, 8 and 16 weeks after first acupuncture

3. Severity of anxiety and depression will be graded using the Hospital Anxiety Depression Scale (HADS) at baseline, 4, 8 and 16 weeks after first acupuncture

**Overall trial start date**

01/03/2016

**Overall trial end date**

31/01/2017

**Reason abandoned**

Eligibility

**Participant inclusion criteria**

1. Aged between 18 and 65 years
2. Normal esophagogastroduodenoscopy results within a year
3. Not allowed drug: anti-secretory drugs, antacids, prokinetics, non-steroidal anti-inflammatory drugs and antidepressant drugs during the treatment period
4. No other treatments received during the study
5. Willing to sign written informed consent

**Participant type**

Patient

**Age group**

Adult

**Gender**

Both

**Target number of participants**
Participant exclusion criteria

1. Presence of serious structural disease (disease of heart, lung, liver or kidney), malignant or mental disease
2. Signs of irritable bowel syndrome
3. Surgery related with the gastrointestinal tract
4. Severe coagulopathy
5. Drug or alcohol abuse
6. Pregnant or breastfeeding

Recruitment start date
30/06/2016

Recruitment end date
31/10/2016

Locations

Countries of recruitment
China

Trial participating centre
Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University
Beijing
100010
China

Trial participating centre
Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine
Beijing
100700
China

Trial participating centre
Beijing Friendship Hospital Affiliated to the Capital Medical University
Beijing
100069

Sponsor information
Organisation
Beijing Municipal Science & Technology Commission
**Sponsor details**

Building 2  
No. 7  
Evergreen Road  
Haidian District  
Beijing  
100195  
China

**Sponsor type**

Government

**Website**

Funders

**Funder type**

Government

**Funder name**

Beijing Municipal Science & Technology Commission

**Alternative name(s)**

**Funding Body Type**

**Funding Body Subtype**

**Location**

Results and Publications

**Publication and dissemination plan**

Planned publication in a peer reviewed journal.

**Intention to publish date**

31/03/2017

**Participant level data**

Not expected to be available

**Results - basic reporting**

**Publication summary**

**Publication citations**

Additional files

**Editorial Notes**