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Acupuncture for postprandial distress syndrome (PDS)

Submission date 20/04/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/07/2016	**Overall study status** Completed	
Last Edited 10/02/2020	**Condition category** Digestive System	

Plain English summary of protocol

Background and study 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 effectiveness 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

Contact information

Type(s)
Scientific

Contact name
Mr Cun-Zhi Liu

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100010

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Z161100000516007

Study information

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

Acronym
APDS

Study objectives

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
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

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Postprandial distress syndrome (PDS)

Interventions
Participants will be randomly assigned to verum acupuncture at acupoints or minimal acupuncture at non-acupoints in a 1:1 ration

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), Zusanli(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 participans in either group. The study will include 4 weeks treatment and 12 weeks follow-up.

Intervention Type
Other

Primary outcome measure
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 study start date
01/03/2016

Completion date
31/01/2017

Eligibility

Key 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(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
42

Total final enrolment
42

Key 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

Date of first enrolment
15/07/2016

Date of final enrolment
31/10/2016

Locations

Countries of recruitment
China

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

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

Study participating centre

Beijing Friendship Hospital Affiliated to the Capital Medical University
Beijing
China
100069

Sponsor information

Organisation
Beijing Municipal Science & Technology Commission

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

Sponsor type
Government

ROR
https://ror.org/034k14f91

Funder(s)

Funder type
Government

Funder Name
Beijing Municipal Science & Technology Commission

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/03/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/11/2017		Yes	No
Results article	results	01/10/2020	10/02/2020	Yes	No