ISRCTN99395260 https://doi.org/10.1186/ISRCTN99395260

Acupuncture clinical trial for chronic persistent moderate bronchial asthma

Submission date	Recruitment status	[ ] Prospectively registered
28/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/07/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/07/2010	Respiratory	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2009CB522708

Study information

Scientific Title

Basic research according to Zang Fu theory about "lungs and large intestine exterior-interior relationship", based on the study of the lungs and large intestine connection through their meridian points having an exterior-interior relationship with common therapeutic effects: a pilot trial

Acronym
ATBA (Acupuncture Trial Bronchial Asthma)

Study objectives
Lung and large intestine are interior-exterior related through the multiple linking in the meridian system. Acupoints concerned with the lung and acupoints concerned with the large intestine have synergic effects when used together, and have the function of treating each other's disorders. Therefore, asthma, a disorder of the lung in Traditional Chinese Medicine (TCM), can be treated with points concerned with the large intestine.

Lung and large intestine have an exterior-interior relationship by way of an "extended meridian network". Points pertaining to the lung and large intestine system have efficient therapeutic effects with common indications or complementary treatment actions; thus asthma, a condition pertaining to lungs system, can be treated using large intestine system points.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of the Beijing University of Chinese Medicine approved on the 15th October 2009 (ref: ECPJ-BDY-2009-10-15)

Primary study design
Interventional

Study design
Randomised controlled pilot trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Asthma

Interventions
Intervention: Acupuncture
Co-intervention: Ventolin inhaler. Patient will use inhalation when necessary.

This study involves patients with chronic persistent moderate bronchial asthma meeting the inclusion criteria. Randomisation was applied to assign participants into four groups:

Group 1:
The first group includes participants that will receive treatment according to the lung system with corresponding acupuncture points (main points: Chize LU5, Kongzui LU6, Lieque LU7, Feishu BL13; associated points: Taiyuan LU9, Yuji LU10, Zhongfu LU1).

Group 2:
The second group includes participants that will receive treatment according to the large intestine system with corresponding acupuncture points (main points: Quchi LI 11, Hegu LI 4, Tianshu ST25, Shangjuxu ST37; associated points: Pianli LI6, Wenliu LI7, Dachangshu BL25).

Group 3:
The third group includes participants that will receive treatment according to both lung and large intestine system with corresponding acupuncture points (main points: Chize LU5, Kongzui LU6, Lieque LU7, Feishu BL13; associated points: Quchi LI 11, Hegu LI 4, Tianshu ST25, Shangjuxu ST37).

Group 4:
The fourth group, not undergoing treatment, is used as the control group.

All the subjects in the above four groups are equipped with Ventolin inhaler, it is allowable to use the inhaler when the subjects feel necessary, but the dosage of the inhaler will be recorded in the Patient Diary and Asthma Control Test (ACT).

Duration of acupuncture session (needle retention time): 30 minutes distributed as 15 minutes in dorsal decubitus and 15 minutes in ventral decubitus
Frequency of acupuncture session: 3 times a week
Duration of treatment: 3 months (36 acupuncture sessions)
Total duration of follow-up for the 3 acupuncture groups: 1 month following the 3 months treatment

Because there is no intervention on the control group besides the use of inhaler when necessary, no follow-up will be done on the control group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Evaluation indicators of clinical efficacy:
1.1. Asthma grading criteria according to the Guide for Prevention and Treatment of Asthma 2008: totally controlled, partly controlled, uncontrolled
1.2. Pulmonary function: forced vital capacity (FVC), FEV1, PEF, maximal mid-expiratory flow rate (MMFF), 50% of vital capacity peak expiratory flow rate (V50) and 25% of vital capacity peak expiratory flow rate (V25). Each test should be repeated three times retaining the best scores as basic values. Pulmonary function tests should be carried out before treatment and 1 - 3 days after the third treatment course. FEV1 indicates the function of both the large and small air passage, especially the large air passage. MMFF, V50, V25 indicate the problems of small air passage and PEF indicates problem of large air passage.
1.3. Evaluation of Chinese Medicine clinical pattern changes in asthma before and after treatment, using asthma evaluation scales:
1.3.1. Asthma Control Questionnaire (ACQ) used to evaluate the patient asthmatic condition within the past week
1.3.2. Asthma Control Test (ACT) used to evaluate the patient asthmatic condition within the past four weeks

1.3.3. Asthma Quality of Life Questionnaire (AQLQ) used to evaluate the asthmatic patient quality of life within the past two weeks
1.4. Patient diary: should contain night time wakening episodes, morning asthma symptoms, movement restriction, dyspnoea, wheezing, number of inhalations and PEF value

2. Impact on asthma pathogenesis:
2.1. Immunological impact: differences in the serum levels of interleukin-4 (IL-4), interleukin-5 (IL-5) and immunoglobulin E (IgE) before and after treatment
2.2. Impact on airways inflammation: difference in serum eosinophil (EOS) count and serum eosinophil cationic protein (ECP) levels before and after treatment
2.3. Impact on the pituitary-hypothalamic-adrenal axis: difference in serum cortisol level before and after treatment

Key secondary outcome(s)
Adverse reaction and safety evaluation
1. Reporting adverse reaction: circumstances of adverse reaction due to improper manipulation technique, should be recorded in details in the specific adverse reaction questionnaire (condition, symptoms, occurrence date, duration). Unrecorded data will be considered as subjective symptoms. Any adverse effect occurring during the trial should be accurately reported and recorded.
2. Reporting adverse reaction: symptoms following acupuncture needling (type, timing, severity, localisation, cause and effect relation. etc.) should be recorded and filed. Its content should be based on clinical trial management standards and stated in the patient case report form.

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Subjects diagnosed as persistent moderate bronchial asthma according to its chronic and persistent characteristics
2. Subjects with recurrent wheezing, breathlessness, chest tightness or cough experienced persistently over a period of six months and within ten years
3. Positive bronchial dilation test: more than 12% increase in forced expiratory volume in one second (FEV1) and more than 200 ml increase in FEV1 absolute value
4. Age range: 18 - 60 years
5. Inclusion of both sexes
6. Subjects having the capacity to describe their consent, voluntarily fill in the informed consent form and agree to participate in the clinical trial
7. Subjects that do not correspond to the exclusion criteria and meet the above requirements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Subjects affected by respiratory tract infection, cardiac asthma, chronic asthmatic bronchitis, lung cancer, allergic pulmonary infiltration that may lead to wheezing
2. Subjects with history of life threatening asthma with tracheal intubation and mechanical ventilation
3. Subjects with acute asthma episode in the past month (showing abrupt onset of wheezing, cough, chest tightness or severe worsening of previous symptoms such as dyspnoea characterised by reduced expiratory flow and often due to irritative agents such as allergen in exposure or inappropriate treatment. Severity varies with condition worsening that can appear within hours or days, with incidental life threatening episodes that can occur in minutes).
4. Subjects with severe dependence on beta-2-adrenergic receptor agonists exceeding 4 inhalations (8 sprays) per day
5. Subjects with apparent thoracic malformation, organic lung disease or lobectomy
6. Subjects suffering from coexistent cardiac diseases or arrhythmia
7. Subjects with coexistent hyperthyroidism
8. Subjects suffering from infectious conditions such as tuberculosis, hepatitis or with creatinine or aspartate aminotransferase (AST)/alanine aminotransferase (ALT; GPT) twice higher than normal values
9. Subjects taking glucocorticoid medication orally (per os) or intravenously within the past month or by inhalation within the past week
10. Subjects on H1 antihistamine or leukotriene antagonist medication per os within the last 14 days
11. Subjects taking specific immunotherapy within the past year
12. Subjects with average peak expiratory flow (PEF) greater than or equal to 80% one week previous to acupuncture and with mutation rate of PEF less than 20%, or average PEF less than 60%
13. Subjects undergoing the following therapies, within the last month to treat their asthma:
13.1. Acupuncture, moxibustion, cupping, nasal inhalation or per os medication with Chinese medicine or other type of folk medicine within the last week
13.2. History of asthma homeopathic treatment or other type of complementary medicine
14. Subjects having taken part in other clinical trials within the last six months
15. Pregnant or breastfeeding women or women of childbearing potential planning pregnancy
16. Subjects with skin lesions on the needling site or suffering from diseases incompatible with needling
17. Subjects with night time occupation
18. Subjects that cannot sustain the trial requirement of three weekly acupuncture sessions during the three month treatment or that are considered unsuitable by the staff in charge of the trial

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
China

Study participating centre
Department of Acupuncture
Beijing
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100700

Sponsor information

Organisation
Ministry of Science and Technology (China)

ROR
https://ror.org/027s68j25

Funder(s)

Funder type
Government

Funder Name
Ministry of Science and Technology (China) - National Basic Research Programme (ref: 2009CB522708)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration