ISRCTN83971033 https://doi.org/10.1186/ISRCTN83971033

The effect of acupoint application therapy in children with chronic coughs of varying severity

Submission date 22/07/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 24/07/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 23/07/2025	**Condition category** Signs and Symptoms	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study was designed to explore the effects of acupoint application on chronic cough of differing pain severity, based on validation of its efficacy in chronic cough, thereby guiding the clinical application of this therapy.

Who can participate?
Children aged 4 to 12 with chronic cough

What does the study involve?
Children with chronic cough were randomly divided into a control group and an observation group. Before receiving treatment, all participants underwent evaluation of cough symptoms and pain levels, which were used as baseline data to assess efficacy.

Control Group: After 2 weeks of diagnostic bronchodilator therapy and empirical inhaled corticosteroids (ICS), a reassessment was performed. Treatment involved a single medication or a combination of two to three medications administered via nebulisation, with dosages and methods adjusted according to clinical needs, along with routine symptomatic treatments for allergies, spasms and asthma.
Observation Group: In addition to the treatment given to the control group, the observation group underwent acupoint application therapy. Referencing the external treatment methods for cough (the syndrome of qi deficiency of the lung and spleen) outlined in the national textbook Pediatrics in Chinese Medicine, edited by Wang Shouchuan, the acupoint application was performed as follows: 12 g of cinnamon, 16 g of clove, 10 g of cassia twig, 15 g of frankincense, 10 g of Codonopsis pilosula, 10 g of Astragalus membranaceus and 30 g each of Angelica sinensis, safflower, red peony, chuanxiong and tuberculate Speranskia herb were ground into fine powder (100 mesh) and sealed in a bottle for later use. When used, the powder was mixed with honey to form a paste or shaped into pills the size of peanuts, followed by placing the prepared medicine in the centre of a sterile dressing.
Acupoint Selection: Days 1–2: Pills were used at the acupoints of Tiantu and Danzhong; pastes were used bilaterally at both Dingchuan and Feiyu. Days 3–5: Pastes were used at the acupoints of Zhongwan, Shenque, Qihai and Guanyuan.
Selection of Application Method: The skin was cleaned with alcohol, and the patient lay supine

to ensure stable application of the medicine. The sterile dressing was then placed on the designated acupoints and gently pressed to ensure full contact between the medicine and the acupoints, followed by securing it with adhesive tape. The application was performed once daily and removed after approximately 4 hours, with a treatment course of 5–7 days. The total intervention lasted 2 weeks.

What are the possible benefits and risks of participating?
Benefits: Traditional Chinese medicine can be used as a complementary treatment when conventional treatments are ineffective. Acupoint application is effective in treating chronic cough in children, significantly improving symptoms of chronic cough and increasing patient satisfaction.

Risks: Skin scraping and acupoint application may cause adverse reactions such as skin allergies, nausea, vomiting, and diarrhea.

Where is the study run from?
1. Guangdong Provincial Hospital of Traditional Chinese Medicine, China
2. Guangzhou Twelfth People's Hospital, China

When is the study starting and how long is it expected to run for?
April 2023 to December 2024

Who is funding the study?
1. Guangdong Provincial Hospital of Traditional Chinese Medicine, China
2. Guangzhou Twelfth People's Hospital

Who is the main contact?
Dr Lifang Lei, leifangli_ll70@163.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Lifang Lei

Contact details
No. 111, Dade Road, Yuexiu District
Guangzhou, Guangdong
China
511400
+86 13543478921
leifangli_ll70@163.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effect of acupoint application therapy

Study objectives
To explore the efficacy of acupoint application therapy in children with chronic coughs of varying severity

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/05/2023, Medical Ethics Committee of Guangzhou No. 12th People's Hospital (No. 111, Dade Road, Yuexiu District, Guangzhou, Guangdong, 511400, China; +86 020-62134001; gz12yy@126.com), ref: 2023082

Study design
Randomized controlled study

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 to request a participant information sheet

Health condition(s) or problem(s) studied
Children with chronic coughs of varying severity

Interventions
One hundred children with chronic cough were randomly divided into a control group (n=50) and an observation group (n=50).

Participants will be randomly assigned (1:1 ratio) to either group according to a computer-generated sequence, with odd-numbered participants assigned to the control group receiving bronchodilator therapy and empirical inhaled corticosteroids conventional treatment, and even-numbered participants assigned to the observation group receiving acupoint application therapy in addition to conventional treatment.

To avoid the influence of the subjective consciousness of evaluators on the results, two full-time personnel were arranged to conduct efficacy evaluations. The personnel conducting the efficacy evaluation did not participate in other aspects of this study, such as enrolment and intervention.

Before receiving treatment, all participants underwent evaluation of cough symptoms and pain levels, which were used as baseline data to assess efficacy.

Control Group: After 2 weeks of diagnostic bronchodilator therapy and empirical inhaled corticosteroids (ICS), a reassessment was performed.

The following bronchodilators were used:
Ipratropium bromide solution for inhalation (Joincare Pharmaceutical Group Industry Co. Ltd., Approval No.: GYZZ H20203454, product specification: 0.5 mg/vial)
Terbutaline sulphate solution for nebulisation (Joincare Pharmaceutical Group Industry Co. Ltd., Approval No.: GYZZ H20223371, product specification: 5 mg/vial)
Salbutamol sulphate solution for inhalation (Suzhou Homesun Pharmaceutical Co. Ltd., Approval No.: GYZZ H20203292, product specification: 5 mg/vial) Empirical ICS included:
Budesonide suspension for inhalation (Sichuan Purity Pharmaceutical Co. Ltd., Approval No.: GYZZ H20213286, product specification: 1 mg/vial)
Fluticasone propionate (GlaxoSmithKline Pty Ltd., Imported Drug Registration No.: H20170361, product specification: 0.5 mg/vial)

Treatment involved a single medication or a combination of two to three medications administered via nebulisation, with dosages and methods adjusted according to clinical needs, along with routine symptomatic treatments for allergies, spasms and asthma.

Observation Group: In addition to the treatment given to the control group, the observation group underwent acupoint application therapy. Referencing the external treatment methods for cough (the syndrome of qi deficiency of the lung and spleen) outlined in the national textbook Pediatrics in Chinese Medicine, edited by Wang Shouchuan, the acupoint application was performed as follows: 12 g of cinnamon, 16 g of clove, 10 g of cassia twig, 15 g of frankincense, 10 g of Codonopsis pilosula, 10 g of Astragalus membranaceus and 30 g each of Angelica sinensis, safflower, red peony, chuanxiong and tuberculate Speranskia herb were ground into fine powder (100 mesh) and sealed in a bottle for later use. When used, the powder was mixed with honey to form a paste or shaped into pills the size of peanuts, followed by placing the prepared medicine in the centre of a sterile dressing.

Acupoint Selection: Days 1–2: Pills were used at the acupoints of Tiantu and Danzhong; pastes were used bilaterally at both Dingchuan and Feiyu. Days 3–5: Pastes were used at the acupoints of Zhongwan, Shenque, Qihai and Guanyuan.

Selection of Application Method: The skin was cleaned with alcohol, and the patient lay supine to ensure stable application of the medicine. The sterile dressing was then placed on the designated acupoints and gently pressed to ensure full contact between the medicine and the acupoints, followed by securing it with adhesive tape. The application was performed once daily

and removed after approximately 4 hours, with a treatment course of 5–7 days. The total intervention lasted 2 weeks.

Intervention Type
Mixed

Primary outcome measure
Cough symptoms will be measured using the cough symptom diurnal scoring system and cough symptom questionnaire, referencing the Diagnostic Standards for Efficacy of Syndrome in Traditional Chinese Medicine, before treatment and 2 weeks after treatment

Secondary outcome measures
The pain level was measured using a Visual Analog Scale (VAS) before treatment and 2 weeks after treatment

Overall study start date
01/04/2023

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Aged 4–12 years
2. Meeting the relevant diagnostic criteria of both TCM and Western medicine as stated above
3. Obvious organic diseases or other severe complications
4. Patients and their parents or guardians willing to participate in the study and able to provide informed consent.

Participant type(s)
Patient, Carer

Age group
Child

Lower age limit
4 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. Severe respiratory complications, e.g. pneumonia or bronchial asthma
2. Received other specific treatments for cough, e.g. antibiotic therapy or immunomodulatory therapy, within the past 3 months
3. Unable to cooperate with acupoint application procedures due to age, cognitive ability or other reasons

Date of first enrolment
01/06/2023

Date of final enrolment
30/10/2024

Locations

Countries of recruitment
China

Study participating centre
Guangzhou no.12 People's Hospital
No. 111, Dade Road, Yuexiu District
Guangzhou, Guangdong
China
511400

Sponsor information

Organisation
Guangdong Provincial Hospital of Traditional Chinese Medicine

Sponsor details
No. 111, Dade Road, Yuexiu District
Guangzhou, Guangdong
China
511400

Sponsor type
Hospital/treatment centre

Website
https://www.gdhtcm.com/

ROR
https://ror.org/01gb3y148

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guangdong Provincial Hospital of Traditional Chinese Medicine

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Funder Name
Guangzhou Twelfth People’s Hospital

Results and Publications

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

Intention to publish date
30/10/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available