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The effect of a Chinese herbal formula on the quality of life and immune system of people who have asthma, a condition where the immune system overreacts to allergens or environmental stimuli and causes symptoms like cough, wheezing and shortness of breath

Submission date
09/04/2025

Recruitment status
No longer recruiting

Registration date
12/04/2025

Overall study status
Completed

Last Edited
11/04/2025

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Asthma is a chronic inflammatory condition affecting the lower airways, characterized by symptoms such as coughing, wheezing, shortness of breath, and chest tightness. This condition significantly impacts quality of life and imposes substantial medical burdens.
In this study, we aimed to investigate if a Chinese herbal formula-BZYQT could be a complementary treatment for asthma by improving patients' quality of life and modulating their immunity.

Who can participate?
Male and female patients aged 20 to 65 years with controlled or partly controlled asthma, diagnosed according to the Taiwan Asthma Guidelines (based on the 2009 GINA revision).

What does the study involve?
Participants were randomly assigned in a 1:1 ratio to receive either oral medication of BZYQT or placebo for 12 weeks. They were scheduled for four visits to the outpatient clinic to assess quality of life questionnaire and blood sample collection.

What are the possible benefits and risks of participating?
The medication used may relieve symptoms of asthma and improve quality of life. Side effect may include dry mouth but without severe side effects.

Where is the study run from?
The traditional Chinese medicine department of Taoyuan, Linkou and Taipei Chang Gung Memorial Hospital in Taiwan.

When is the study starting and how long is it expected to run for?
November 2016 to December 2021

Who is funding the study?
This work was supported by the Chang-Gung Medical Foundation (Taiwan) (grant number: CMRPG1G0091, CMRPG1G0092, CMRPG1G0093)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Evaluation of Bu-Zhong-Yi-Qi-Tang (BZYQT) on quality of life and immune modulation in asthma patients: a randomized, double-blind, placebo-controlled pilot trial

Study objectives
BZYQT improves asthma-related quality of life and modulates immune and inflammatory responses.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/11/2016, Medical Ethics and Human Clinical Trial Committee of Chang Gung Memorial Hospital (No. 123, Dinghu Rd., Guishan Dist., Taoyuan, 333008, Taiwan; +886-3-3196200 #3712; shihhua@cgmh.org.tw), ref: CGMH IRB No.201601139A3

Study design
Multicentre interventional randomized double-blind placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Treatment with a Chinese herbal formula for patients with asthma

Interventions
Patients with asthma were randomly assigned to receive either BZYQT (oral, 12 grams per day) or placebo for 12 weeks.

Total duration of follow-up for all study arms: 16 weeks

Details of the randomisation process:
Eligible participants were randomly assigned to either the study or control group in a 1:1 ratio. Each participant was assigned a unique project number by the researchers. The randomization code list was generated using a permuted block randomization method by Chuang Song Zong Pharmaceutical Co., Ltd.. The manufacturer labeled the study capsules with identical appearances based on the randomization code list. Our hospital pharmacy then received these capsules, numbered consecutively and randomized as either BZYQT or placebo. The pharmacists dispensed the capsules to participants based on their project number.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Bu-Zhong-Yi-Qi-Tang (BZYQT)

Primary outcome(s)
Quality of life, measured using the Asthma Quality of Life Questionnaire (AQLQ) at week 0 (before receiving BZYQT or placebo), week 6 (six weeks after starting BZYQT or placebo), week 12 (12 weeks after starting BZYQT or placebo, end of treatment), and week 16 (end of the trial)

Key secondary outcome(s))
1. Immune and inflammatory markers such as IgE, eosinophil counts, measured by blood sample at weeks 0,6,12, and 16
2. Asthma-related cytokines (IL-4, IL-5, IL-10, and IL-13), and inflammatory mediators (IL-8, LTC4,

sICAM-1, and PGE2) measured by blood sample at weeks 0,6, and 12
3. Safety profiles, including CBC and liver and kidney function (ALT and creatinine), were also carried out at weeks 0,6,12, and 16

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Patients aged between 20 and 65 years with controlled or partly controlled asthma.
2. Diagnosed according to the Taiwan Asthma Guidelines (based on the 2009 GINA revision).
3. Participants were required to be capable of correctly performing pulmonary function tests (spirometry).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 years

Upper age limit
65 years

Sex
All

Total final enrolment
44

Key exclusion criteria
1. Patients currently undergoing treatment with oral or injectable corticosteroids, or other immunomodulatory agents.
2. Patients who had discontinued such medications within one month prior to the study.
3. Individuals with active infectious diseases, including pneumonia, sinusitis, or bronchitis.
4. Patients with dementia or other psychiatric disorders that could interfere with their ability to complete the required study questionnaires.
5. Individuals with a history of allergy to TCM, poor medication adherence, or a history of previous adverse reactions.
6. Patients with severe organ dysfunction, such as heart failure, liver failure, liver cirrhosis, or chronic kidney disease with an estimated glomerular filtration rate (eGFR) of less than 60 mL/min /1.73 m^2.

Date of first enrolment

21/01/2019

Date of final enrolment
18/12/2021

Locations

Countries of recruitment
Taiwan

Study participating centre
Taoyuan Chang Gung Memorial Hospital
No. 123, Dinghu Rd. Guishan Dist.
Taoyuan
Taiwan
333008

Study participating centre
Linkou Chang Gung Memorial Hospital
No.5, Fuxing St. Guishan Dist.
Taoyuan
Taiwan
333423

Study participating centre
Taipei Chang Gung Memorial Hospital
No. 199, Dunhua N. Rd., Songshan Dist.
Taipei
Taiwan
105406

Sponsor information

Organisation
Taoyuan Chang Gung Memorial Hospital

ROR
https://ror.org/00fk9d670

Funder(s)

Funder type
Charity

Funder Name
Chang Gung Medical Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan
The data that support the findings of this study are available from the corresponding author upon reasonable request.
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IPD sharing plan summary
Available on request