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# The effect of a mixed Chinese herbal formula on the immune system of people who have perennial allergic rhinitis, a condition where the immune system overreacts to year-round allergens and causes symptoms like sneezing and congestion in the nose

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| **Submission date**<br>05/06/2023 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>07/06/2023 | **Overall study status**<br>Completed | |
| **Last Edited**<br>07/06/2023 | **Condition category**<br>Ear, Nose and Throat | |

## Plain English summary of protocol

Background and study aims

In Taiwan, the number of people with allergic rhinitis (AR, a condition where the immune system overreacts to year-round allergens and causes symptoms like sneezing and congestion in the nose) has been rising. Doctors often prescribe mixed Chinese herbal formulas (CHFs) rather than single herbs to treat AR. However, there is limited research on how these mixed CHFs work. In this study, we aimed to understand how mixed CHFs affect the immune system in treating AR by looking at their effects on special immune cells called regulatory B cells and levels of certain proteins called cytokines.

Who can participate?

Male and female patients aged 20 to 65 years with a clinical history of perennial allergic rhinitis characterized by rhinorrhea, sneezing, nasal itching, or nasal obstruction, occurring for an hour or more on most days throughout the year

What does the study involve?

All participants receive mixed CHFs treatment for 3 months. Blood samples from patients with perennial AR were collected and measured for the number of regulatory B cells and immune cytokine levels after mixed CHFs treatment for 3 months.

What are the possible benefits and risks of participating?

The medication used may relieve symptoms of allergic rhinitis such as rhinorrhea, sneezing, nasal itching, or nasal obstruction. Side effect may include dry mouth but without severe side effects.

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

When is the study starting and how long is it expected to run for?
January 2015 to July 2017

Who is funding the study?
This work was supported by the Taiwan Ministry of Science and Technology (grant number 104-2320-B-182-007-MY2)

Who is the main contact?
Prof. Sien-Hung Yang, dryang@mail.cgu.edu.tw

# Contact information

### Type(s)
Principal investigator

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
Nil known

# Study information

### Scientific Title
Immunomodulatory effects of a mixed Chinese herbal formula on perennial allergic rhinitis patients with high IgE levels via regulatory B cells

## Study objectives
Regulatory B cells and immune-regulatory cytokines were involved in the immune modulation with mixed Chinese herbal formula treatment for patients with allergic rhinitis.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 23/04/2015, Medical Ethics and Human Clinical Trial Committee of Chang Gung Memorial Hospital (No. 123, Dinghu Rd., Guishan Dist., Taoyuan City 333008, Taiwan; no telephone number provided; yjding@cgmh.org.tw), ref: CGMH IRB No. 103-6851A3

## Study design
Multicentre interventional non-randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Treatment with a mixed Chinese herbal formula for patients with allergic rhinitis

## Interventions
Patients suffering from perennial allergic rhinitis (AR; characterized by rhinorrhea, sneezing, nasal itching, or nasal obstruction occurring for an hour or more on most days throughout the year) and eligible for inclusion and exclusion criteria were enrolled.
The patients were divided into two groups. Those with high total serum IgE levels (≥ 200 IU/mL) were assigned to the H-IgE group, and those with low total serum IgE levels (< 200 IU/mL) were assigned to the L-IgE group. The patients with H-IgE levels were hypersensitive to dust mites or other common allergens, such as cats and dogs, as confirmed using a multiple allergen simultaneous test (MAST), while the patients with L-IgE levels were with or without sensitivity to allergens.
All patients in both the H- and L-IgE groups were treated with a mixed CHF composed of Xin-yi-san + Xiao-qing-long-tang + Xiang-sha-liu-jun-zi-tang at a ratio of 3:1:1 in powder form. Participants were instructed to take 5 g of the powder orally thrice a day after each meal for three months. We measured the number of regulatory B cells and the expression of CD1d, CD80, and CD86 using flow cytometry after mixed Chinese herbal formula treatment for 3 months. We also investigated the effects of mixed Chinese herbal formula on cytokine expression using a cytometric bead array by co-culturing Breg cells with CD4+CD25- T cells from patients with allergic rhinitis.

## Intervention Type
Drug

## Phase
Phase II

## Drug/device/biological/vaccine name(s)

Xin-yi-san, Xiao-qing-long-tang, Xiang-sha-liu-jun-zi-tang

### Primary outcome(s)
Evaluation of numbers of regulatory B cells and expressions of CD1d, CD80 and CD 86 post stimulation of B cells using flow cytometry before and after 1, 2, and 3 months of mixed Chinese herbal formula treatment

### Key secondary outcome(s))
Evaluation of cytokine expression in the CD19+CD25+ regulatory B cells co-cultured with CD4+CD25- T cells using cytometric bead array before and after 1, 2, and 3 months of mixed Chinese herbal formula treatment

### Completion date
31/07/2017

## Eligibility

### Key inclusion criteria
1. A clinical history of perennial allergic rhinitis characterized by rhinorrhea, sneezing, nasal itching, or nasal obstruction, occurring for an hour or more on most days throughout the year
2. Hypersensitivity to dust mite allergens or other common allergens, as confirmed using a multiple allergen simultaneous test in the high total serum IgE levels (≥ 200 IU/mL) group
3. Male and female patients aged 20 to 65 years
4. Willing to take medicine as scheduled in this study
5. Volunteered for study enrollment and signed informed consent

### 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
49

### Key exclusion criteria
1. Diagnosed as active infectious diseases, such as acute sinusitis, pneumonia, or bronchitis
2. Severe organ dysfunction, such as impaired renal and hepatic function at initial diagnosis

(including chronic kidney disease stages III, IV, and V and AST, ALT ≥ 3 × the upper normal limit), liver cirrhosis, or heart failure
3. Using antihistamine, steroid, leukotriene inhibitors, immunosuppressant, or other Chinese herbal medicine for 1 month before enrollment
4. Women who are pregnant or are planning to conceive

### Date of first enrolment
14/10/2015

### Date of final enrolment
20/07/2016

## Locations

### Countries of recruitment
Taiwan

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

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

## Sponsor information

### Organisation
Taoyuan Chang Gung Memorial Hospital

### ROR
https://ror.org/00fk9d670

# Funder(s)

### Funder type
Government

### Funder Name
Ministry of Science and Technology, Taiwan

### Alternative Name(s)
Ministry of Science and Technology, R.O.C. (Taiwan), Ministry of Science and Technology of Taiwan, MOST

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### 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.
dryang@mail.cgu.edu.tw

### IPD sharing plan summary
Available on request