

# Nasal spray with licorice extract to treat inflammation of the nose and sinuses

<b>Submission date</b> 27/08/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/09/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/09/2022	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Licorice, an ancient Chinese herbal medicine, has been widely studied to have significant anti-inflammatory and immunomodulatory effects for the treatment of various inflammatory diseases. It has a fragrant and sweet taste, and is highly accepted by patients. In the past, we have developed a licorice extract to treat allergic rhinitis via nasal irrigation. According to the results of clinical trials, it was found that its effect and comfort were better than nasal irrigation with corticosteroid. However, steroid nasal sprays are currently one of the main weapons in the treatment of allergic rhinitis. Therefore, we would like to further make this licorice extract to nasal spray and conduct a clinical trial to compare it with a steroid nasal spray to evaluate its efficacy in the treatment of allergic rhinitis.

### Who can participate?

Patients with allergic rhinitis aged 20 years and above

### What does the study involve?

Participants will use either a licorice or corticosteroid (fluticasone) nasal spray at home twice per day over 4 weeks. They will be assessed at the start, middle (2 weeks) and end (4 weeks) of the study for the subjective assessment of their allergic rhinitis symptoms and objective comparison of changes in the degree of swelling of the nasal mucosa before and after treatment.

### What are the possible benefits and risks of participating?

Because we will teach those participants how to use nasal spray correctly by an expert before the study, they will have the benefit to learn the skill for further nasal care. In addition, any kind of intervention (NSLE or NSCS) would be supposed to improve their nasal symptoms by degrees. According to our preliminary study, nasal spray with licorice extract was considered safe without adverse effects.

### Where is the study run from?

Chiayi Chang Gung Memorial Hospital (Taiwan)

### When is the study starting and how long is it expected to run for?

April 2022 to August 2025

Who is funding the study?  
Chiayi Chang Gung Memorial Hospital (Taiwan)

Who is the main contact?  
Geng-He Chang, MD, genghechang@gmail.com

## Contact information

### Type(s)

Principal Investigator

### Contact name

Dr Geng-He Chang

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

MOST111-2320-B-182A-010

## Study information

### Scientific Title

Investigating the effect of nasal spray with extract of licorice on treatment of allergic rhinitis

### Acronym

NSLE

**Study objectives**

The anti-inflammatory and immunomodulatory effects of licorice have been well-studied. We hypothesize that nasal spray with licorice extract has equal or better effect on the treatment of allergic rhinitis than nasal spray with corticosteroid steroid

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 01/07/2022, Institutional Review Board (IRB) of Chang Gung Medical Foundation (No. 199, Dunhua N. Rd., Songshan Dist., Taipei City 105, Taiwan R.O.C; +886-3-3196200 ext.3708; ccyi@cgmh.org.tw), ref: 202102081A3

**Study design**

Single-center interventional non-blinded randomized parallel trial

**Primary study design**

Interventional

**Secondary study design**

Randomised parallel 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 patient information sheet.

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

Treatment of patients with allergic rhinitis

**Interventions**

This study is expected to include patients with allergic rhinitis. The patients will be sequentially assigned to two groups, one using nasal spray with licorice extract and the other using nasal spray with corticosteroid. Patients in both groups use the assigned treatment twice a day with one spray for each nostril for one month, and return to the clinic every two weeks, for a total of two follow-ups.

**Intervention Type**

Drug

**Phase**

Phase II

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

Licorice extract, fluticasone furoate

**Primary outcome measure**

The four main symptoms of allergic rhinitis (sneezing, itchy nose, rhinorrhea, and nasal obstruction) are evaluated using a visual analogue scale (0-100) before treatment, at two weeks and four weeks. In addition, SNOT-22 is also used to evaluate 22 allergic rhinitis-related symptoms in patients, and the scores are summed to compare the improvement of the total score before treatment and at two and four weeks.

**Secondary outcome measures**

We used acoustic rhinometry to assess the improvement in nasal resistance before and after treatment, record and compare the improvement of the inferior turbinate hypertrophy before and after treatment with endoscopy, and collect nasal secretions to investigate the changes of intranasal microenvironment before and after treatment were analyzed and compared. All three measurements are assessed before treatment and at two and four weeks of treatment.

**Overall study start date**

01/04/2022

**Completion date**

31/08/2025

**Eligibility****Key inclusion criteria**

Patients with allergic rhinitis; the diagnostic criteria require a visual analogue scale (0-100) in the four categories of sneezing, itchy nose, rhinorrhea and nasal obstruction with a summed score greater than 120, and immunoglobulin E greater than 120 kU/L, and more than one inhalation allergen, such as dust.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

120

**Key exclusion criteria**

1. Patients aged less than 20 years
2. A history of allergy to licorice or corticosteroid
3. Pregnancy
4. A history of malignancies of the sinuses or nasopharynx
5. Patients who had undergone turbinate, septum or sinus surgery
6. If steroids or antihistamines is used in the month prior to inclusion, one month of cessation is required to conduct the trial.

**Date of first enrolment**

07/09/2022

**Date of final enrolment**

30/06/2025

## **Locations**

**Countries of recruitment**

Taiwan

**Study participating centre**

**Chiayi Chang Gung Memorial Hospital**

Department of Otolaryngology – Head and Neck Surgery

Chiayi Chang Gung Memorial Hospital

No.8, W. Sec.

Jiapu RD.

Puzi

Taiwan

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## **Sponsor information**

**Organisation**

Chiayi Chang Gung Memorial Hospital

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.cgmh.org.tw/tw/Services/DeptList/6>

**ROR**

<https://ror.org/04gy6pv35>

# 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

## Publication and dissemination plan

This trial will run for 3 years. If the research data is collected in advance, we will analyze the data and write articles for publication on high-impact peer-reviewed journal.

## Intention to publish date

31/08/2026

## Individual participant data (IPD) sharing plan

The individual participant data collected by this study will not be published directly online, but the analysis results will be presented in subsequent publications. Scholars who need the information of IPD can write directly to Geng-He Chang for inquiries, genghechang@gmail.com

## IPD sharing plan summary

Available on request