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

Submission date
27/08/2022

Recruitment status
No longer recruiting

Registration date
01/09/2022

Overall study status
Completed

Last Edited
02/02/2026

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Single-center interventional non-blinded randomized parallel trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
0

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
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Sponsor information

Organisation
Chiayi Chang Gung Memorial Hospital

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/01/2026	02/02/2026	Yes	No