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Comparing an oral anti-allergy medicine alone versus in combination with a nasal spray for treating allergic rhinitis in children

Submission date 01/12/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 03/12/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 02/12/2025	**Condition category** Respiratory	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Allergic rhinitis (hay fever) is a very common problem in children. It can cause sneezing, runny or blocked nose, itching, cough and poor sleep, which may affect school performance and quality of life.

Desloratadine (desloratadine citrate) is an oral anti-allergy medicine that is often used to treat allergic rhinitis in children, but some children still have symptoms or improve slowly with this medicine alone. Fluticasone propionate nasal spray is a corticosteroid “nose spray” that can reduce inflammation and allergy in the nose.

The aim of this study is to find out whether using fluticasone propionate nasal spray together with desloratadine works better than desloratadine alone in children with allergic rhinitis, and whether the combination is safe. The study will also look at lung function and immune markers in the blood to better understand how the treatment works.

Who can participate?

Children aged 4–10 years old who have been diagnosed with allergic rhinitis according to standard guidelines, with typical symptoms such as sneezing, runny nose, nasal itching or nasal blockage.

What does the study involve?

This is a randomised study. That means children who agree to join are randomly allocated (like flipping a coin) to one of two groups:

Control group: takes desloratadine dry suspension by mouth once a day (2.5 mg per day for 4–10-year-olds) for 4 weeks.

Observation group: takes the same desloratadine by mouth plus fluticasone propionate nasal spray (one spray in each nostril once a day, total 100 micrograms per day) for 4 weeks.

During the 4-week treatment period, children are not allowed to use other medicines that might affect the results, such as other corticosteroids, other antihistamines, leukotriene receptor blockers or nasal decongestants.

Before the study starts, a member of the research team will show parents exactly how to use the nasal spray and check that they can use it correctly. Parents may be given a treatment diary or receive phone reminders to help record how the medicine is used and to monitor adherence.

The study includes:
1. Symptom scores: A total nasal symptom score (TNSS) will be recorded before treatment, at the end of 4-week treatment, and again at 1 month and 3 months after treatment (by clinic visit or phone follow-up). The TNSS rates sneezing, runny nose, nasal itching and nasal blockage from 0 (no symptoms) to 3 (severe).
2. Clinical effectiveness: The research team will classify the response as “markedly effective”, “effective” or “ineffective” based on symptom improvement and nasal examination.
3. Lung function tests: A lung function machine will measure FEV1% predicted (how much air a child can blow out in one second compared to the expected value) before treatment, at 4 weeks, and at 1 and 3 months after treatment.
4. Blood tests: Small blood samples will be taken before and after the 4-week treatment to measure inflammatory markers (IL-2, IL-4, IFN-γ) and immune cell markers (T-cell subsets such as CD3+, CD4+, CD8+, CD4+/CD8+ and regulatory T cells, Treg).
5. Safety monitoring: Any side effects (such as diarrhoea, cough, fever or nosebleeds) will be recorded in both groups.
The study uses single-blind assessment: the person who scores the symptoms and evaluates the results does not know which treatment the child received. 4

What are the possible benefits and risks of participating?
Possible benefits:
Children may have better control of nasal symptoms, such as less sneezing, runny nose and nasal blockage.
The combination treatment may help improve lung function and support immune balance in the body.
Even if a child does not benefit personally, taking part may help doctors learn which treatments work best for children with allergic rhinitis in the future.

Possible risks:
Both desloratadine and fluticasone nasal spray are widely used medicines and are generally well tolerated. However, they may cause side effects such as:
Mild nasal irritation or nosebleeds; Cough, headache or mild fever; Stomach discomfort or diarrhoea; Very rarely, allergic reactions; Blood tests may cause brief pain, bruising or discomfort at the needle site.
All participants will be monitored closely. Any side effects will be recorded and treated as needed. Parents can withdraw their child from the study at any time without affecting the child’s usual medical care.

Where is the study run from?
Department of Pediatrics, The Affiliated Huaian No.1 People’s Hospital of Nanjing Medical University, Huaian City , Jiangsu Province, China

When is the study starting and how long is it expected to run for?
December 2023 to June 2025.

Who is funding the study?
The Affiliated Huaian No.1 People’s Hospital of Nanjing Medical University, China.

8.Who is the main contact?
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Study information

Scientific Title
Clinical efficacy of fluticasone propionate nasal spray combined with desloratadine citrate in children with allergic rhinitis and its effects on lung function and immune function: a randomized controlled study

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/03/2022, Ethics Committee of The Affiliated Huaian No.1 People's Hospital (Huanghe West Road, Huaiyin District, Huaian City, 223300, China; +86 (0)51784936880; Su124jau2138@163.com), ref: KY-2022-021-01

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Allergic rhinitis in children (pediatric allergic rhinitis)

Interventions
This is a single-centre, randomised, parallel-group controlled clinical study.

Participants will be randomly in a 1:1 ratio to either the control group or the observation group using a computer-generated random number (random number table) sequence prepared by an independent researcher. Allocation will be concealed in sequentially numbered, sealed envelopes. Outcome assessors will be blinded to group assignment (assessor-blind design).

Control group (desloratadine citrate only): Participants in the control group will receive oral desloratadine citrate dry suspension (manufactured by Yangtze River Pharmaceutical Group Guangzhou Hairui Pharmaceutical Co., Ltd.; Chinese NMPA approval number H20090138). The dry suspension will be dissolved in an appropriate volume of water immediately before administration. Children aged 4–10 years will receive 2.5 mg (1 sachet) once daily by mouth for a total treatment duration of 4 weeks.

Observation group (fluticasone propionate nasal spray + desloratadine citrate): Participants in the observation group will receive the same desloratadine citrate regimen as the control group, combined with intranasal fluticasone propionate nasal spray (Glaxo Wellcome S.A., Tres Cantos, Madrid, Spain; Chinese NMPA approval number HJ20140117). Fluticasone propionate nasal spray will be administered as 1 spray (50 μg) into each nostril once daily (total daily dose 100 μg) for 4 weeks. Before the start of treatment, caregivers will be instructed and trained by study staff on the correct use of the nasal spray device.

During the 4-week treatment period, the use of other systemic or intranasal corticosteroids, antihistamines, leukotriene receptor antagonists, or nasal decongestants that may affect efficacy assessment will be prohibited in both groups.

Medication adherence will be monitored using medication diaries and/or regular telephone reminders. All participants will undergo baseline assessments before treatment initiation and repeated evaluations at the end of the 4-week treatment period. In addition, follow-up assessments will be performed at 1 month and 3 months after completion of treatment to evaluate the persistence of therapeutic effects.

The following outcome measures will be collected:
(1) Allergic rhinitis symptom score: The Total Nasal Symptom Score (TNSS) will be used to assess nasal symptoms (sneezing, rhinorrhoea, nasal itching, nasal congestion), scored on a 0–3 scale for each item (0 = none, 3 = severe). TNSS will be measured at baseline, at the end of treatment, and at 1 and 3 months after treatment to evaluate short- and medium-term efficacy.
(2) Clinical efficacy: Clinical response will be classified as markedly effective, effective, or ineffective according to the percentage reduction in TNSS compared with baseline. Total effective rate will be calculated as (markedly effective + effective) / total × 100%.
(3) Pulmonary function: Forced expiratory volume in 1 second as a percentage of predicted value (FEV1% predicted) will be measured using a spirometer at baseline, at the end of treatment, and at 1 and 3 months after treatment.
(4) Inflammatory cytokines: At baseline and at the end of treatment, venous blood samples will be collected, and serum levels of interleukin-2 (IL-2), interleukin-4 (IL-4) and interferon-γ (IFN-γ) will be determined using enzyme-linked immunosorbent assay (ELISA).
(5) Cellular immune function: At baseline and after 4 weeks of treatment, fasting venous blood (5 mL) will be collected to measure T-lymphocyte subsets including CD3, CD4, CD8, CD4/CD8 ratio, and regulatory T cells (Treg) using flow cytometry.
(6) Safety / Adverse events: Adverse events, including but not limited to diarrhoea, cough, fever, and epistaxis, will be recorded throughout the study period in both groups. The incidence and severity of adverse events will be compared between groups to evaluate the safety of the interventions.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Fluticasone propionate nasal spray; Desloratadine citrate dry suspension

Primary outcome(s)
1. Sneezing, rhinorrhea, nasal itching and nasal congestion measured using the Total Nasal Symptom Score (TNSS) 4-point scale at baseline (pre-treatment), end of treatment (4 weeks), and at 1 month and 3 months after completion of treatment.

2. Overall clinical efficacy rate measured using the proportion of participants classified as “markedly effective” or “effective” based on percentage reduction in TNSS from baseline (≥90% = markedly effective; 60–90% = effective; <60% = ineffective) at the end of treatment (4 weeks)

3. Lung function forced expiratory volume in 1 second (FEV1% predicted) as a percentage of predicted value (FEV1% pred) measured using spirometry at baseline, end of treatment (4 weeks), and at 1 month and 3 months after completion of treatment.

4. Change in serum inflammatory cytokines levels of IL-2, IL-4 and IFN-γ measured using enzyme-linked immunosorbent assay (ELISA) at baseline and end of treatment (4 weeks)

5. Change in cellular immune function: the proportions of CD3+, CD4+, CD8+ T cells, CD4+/CD8+ ratio and regulatory T cells (Treg) measured using flow cytometry at baseline and end of treatment (4 weeks)

Key secondary outcome(s))
1. Incidence of adverse events measured using the number and proportion of participants experiencing adverse events (including diarrhea, cough, fever, epistaxis and other reported events), as recorded in case report forms at throughout the 4-week treatment period and during follow-up to 3 months after completion of treatment

Completion date
01/06/2025

Eligibility

Key inclusion criteria
1. Met the diagnostic criteria for allergic rhinitis, presenting with symptoms such as nasal itching, clear rhinorrhea, paroxysmal sneezing, and hyposmia
2. Had not used systemic glucocorticosteroids or antihistamines within the 2 weeks prior to enrollment
3. Had complete clinical data and no history of drug allergies
4. The children and their guardians were fully informed and signed the informed consent form
5. Aged 4-10 years

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 years

Upper age limit
10 years

Sex
All

Total final enrolment
200

Key exclusion criteria
1. Concomitant with other nasal diseases such as asthma, nasal polyps, or severe deviated nasal septum
2. History of nasal surgery
3. Accompanied by severe primary diseases of the heart, liver, kidneys, or hematopoietic system
4. Poor adherence to prescribed medication

Date of first enrolment
01/12/2023

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
Affiliated Huaian No. 1 People’s Hospital

Funder(s)

Funder type

Funder Name
Affiliated Huaian No. 1 People’s Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date