

Study on the effectiveness of allergen immunotherapy in patients with house dust mite-induced allergic rhinitis and other associated allergic conditions

Submission date 13/05/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/05/2019	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/05/2019	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Allergen-specific sublingual immunotherapy (SLIT) is an effective disease-modifying treatment for house dust mite-induced allergic rhinitis. However, research on its effectiveness on its concomitant allergic conditions is scarce. As a response, the effectiveness of SLIT in patients with house dust mite (HDM) induced allergic rhinitis, and its concomitant allergic diseases including asthma, allergic conjunctivitis and atopic dermatitis has been evaluated in this study.

Who can participate?

Patients suffering from house dust mite-induced allergic rhinitis.

What does the study involve?

All participants' records in the standardized questionnaire reflecting their progress including their symptoms, medication use and side effect were retrieved and reviewed. Participants were allocated to one of the two groups depending on whether they received sublingual immunotherapy in allergy centre. Participants in the study group received sublingual immunotherapy with house dust mite allergen extract daily for at least 12 months in addition to conventional treatment. Participants in the control group received conventional treatment as usual practice. Symptom scores of allergic rhinitis, asthma, allergic conjunctivitis, and eczema were assessed. The medication usage including antihistamines and nasal topical steroids were also recorded. Any treatment-related side effect during the study period was documented according to the grading system recommended by the World Allergy Organization.

What are the possible benefits and risks of participating?

Participants need to complete a standardized questionnaire each time during their follow up visits for up to 36 months during the study period. Otherwise, there is no additional risk by taking part in this study. All Participants' record data were anonymized.

Where is the study run from?
Allergy Centre of Hong Kong Sanatorium & Hospital

When is the study starting and how long is it expected to run for?
1 March 2019 to 1 March 2021

Who is funding the study?
Allergy Centre of Hong Kong Sanatorium & Hospital

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HKSH RC-2019-06

Study information

Scientific Title

Effectiveness of allergen-specific sublingual immunotherapy for house dust mite-induced allergic rhinitis and its co-morbid conditions

Acronym

N/A

Study objectives

Allergen-specific sublingual immunotherapy is an effective treatment for house dust mite-induced allergic rhinitis, as well as its co-morbid allergic conditions

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/02/2019, Hong Kong Sanatorium & Hospital Research Ethics Committee (Research Ethics Committee, Hong Kong Sanatorium & Hospital, 38/F, Li Shu Pui Block, 2 Village Road, Happy Valley, Hong Kong; +852 2572 0211; hospital@hksh-hospital.com), ref: RC-2019-06.

Study design

Retrospective Case Control Study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

House dust mite induced allergic diseases

Interventions

Patients diagnosed to have house dust mite-induced perennial allergic rhinitis according to ARIA guidelines who received sublingual immunotherapy (SLIT) with sublingual allergen extract for over 12 months were enrolled as case, and controls were age- and sex-matched patients with the same diagnosis who were never treated with SLIT. All enrolled patients will be followed up regularly once every 3 months and given a standardized questionnaire at every visit to record their symptom severity, medication use and treatment-related adverse events. They will be followed-up regularly until 36 months.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

House dust mite sublingual allergen extract

Primary outcome(s)

Symptom scores are measured using a standardized questionnaire at baseline and then every 3 months.

Key secondary outcome(s)

Medication use is measured using a standardized questionnaire at baseline and then every 3 months.

Completion date

01/03/2022

Eligibility

Key inclusion criteria

Suffering from house dust mite-induced perennial allergic rhinitis.

Participant type(s)

All

Healthy volunteers allowed

No

Age group

All

Sex

All

Key exclusion criteria

1. Incomplete records of clinical data.
2. Concurrent systemic immunological disorders.
3. Using immunomodulatory treatment.

Date of first enrolment

01/03/2019

Date of final enrolment

01/03/2021

Locations

Countries of recruitment

Hong Kong

Study participating centre

Hong Kong Sanatorium & Hospital

2 Village Road, Happy Valley, Hong Kong

Hong Kong
Hong Kong
N/A

Sponsor information

Organisation

Hong Kong Sanatorium & Hospital

ROR

<https://ror.org/010mjn423>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hong Kong Sanatorium & Hospital

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other