ISRCTN32263767 https://doi.org/10.1186/ISRCTN32263767

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

Registration date
14/05/2019

Overall study status
Completed

Last Edited
14/05/2019

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
Dr. Alson Chan
awmc@hku.hk

Study website
N/A

Contact information

Type(s)
Scientific

Contact name
Dr Alson Chan

ORCID ID
http://orcid.org/0000-0003-1382-3690

Contact details
Allergy Centre
Hong Kong Sanatorium & Hospital
9/F
Li Shu Pui Block
2 Village Road
Happy Valley
Hong Kong
Hong Kong
N/A
+85228358430
awmc@hku.hk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 it 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

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

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

Overall study start date
01/01/2019

Completion date
01/03/2022

Eligibility

Key inclusion criteria
Suffering from house dust mite-induced perennial allergic rhinitis.

Participant type(s)
All

Age group
All

Sex
Both

Target number of participants
120

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

Sponsor details
2 Village Road
Happy Valley
Hong Kong
Hong Kong
N/A
+852 2572 0211
hospital@hksh-hospital.com

Sponsor type
Hospital/treatment centre

Website
www.hksh.com

ROR
https://ror.org/010mjn423

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hong Kong Sanatorium & Hospital

Results and Publications

Publication and dissemination plan
Study results on primary, secondary and relevant outcomes will be published in a peer reviewed medical journal.

Intention to publish date
01/06/2020

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