Symptom scores and pollen monitoring by hay fever patients (SYMPOL)

Published: 23-03-2018
Last updated: 12-04-2024

Primary Objective: Evaluate the relationship between the amount of pollen collected in the environment of the hay fever sufferers using a handheld sniffer and the symptoms of these subjects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON46378

Source
ToetsingOnline

Brief title
SYMPOL

Condition

- Allergic conditions

Synonym
hay fever

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: RAAK-publiek subsidie (SIA)

Intervention

Keyword: Hay fever, Pollen, Symptoms

Outcome measures

Primary outcome

The relationship between the amount of pollen in the environment of the hay fever suffers measured via the pollensniffer and the severity of their symptoms.

Secondary outcome

Knowledge on the user friendliness of the handheld pollensniffer based on a questionnaire outcome and suggestions for improvements.

Study description

Background summary

For many people, a sunny day in spring or summer means a day with itchy, watery eyes and/or a runny or blocked nose. The pollen in the air on those days causes the nose and eye symptoms in people who are sensitized to that pollen. Importantly, a substantial proportion of individuals with hay fever suffer from severe symptoms, causing impaired quality of life and reduced performance at school and work (Walker et al. 2007). Since so many individuals suffer from hay fever and since these symptoms are frequently associated with other inflammatory diseases such as asthma, the impact and costs for society are significant (Zuberbier et al. 2014).
Symptoms of hay fever sufferers can be monitored by mobile applications and these symptom scores can be related to daily pollen counts supplied by the LUMC (de Weger et al. 2014; de Weger et al. 2011). Currently, these pollen are being counted using a static sampler that is located on the roof of the 6th floor of the LUMC. Little is known about the pollen concentrations that individuals are exposed to. This pilot study aims to correlate symptoms in hay fever sufferers to the measurement of pollen concentrations in the direct environment of the individual.
This study is part of the project *Nie(t)s is te gek*, which is a collaborative study between the University of Applied Science in Leiden (Hogeschool Leiden), Generade, Leiden University Medical Center (Department of Pulmonology and Human

Genetics) and the Leidse Instrumentmakers School. In this project, a handheld pollen sampler was developed, that can collect pollen in the direct environment of the subjects thus enabling personalized monitoring of pollen exposure. This handheld pollen sampler is called pollensniffer. The pollen will be quantified by microscopic counting. Within the project a new analysis method is being developed. When this method is available the samples can be analysed by this new method too. In this pilot study, we aim to investigate (i) whether the amount of grass pollen collected by the handheld pollensniffer correlates with the symptoms of individuals; and (ii) the user-friendliness of the pollensniffer.
For this pilot we aim to recruit 10 participants with hay fever. The sensitization pattern of these study subjects will be tested by a blood test to assess pollen-specific IgE. Only individuals positive for grass pollen will be recruited. These subjects will be asked to (1) monitor their environment in the morning when they go to school or work during approximately 15 min; (2) score their hay fever symptoms by using an app; and (3) not use hay fever medication.

The present pilot study is essential for further development of personalized pollen monitoring, and we aim to use the results in publications and for future grant applications.

Study objective

Primary Objective: Evaluate the relationship between the amount of pollen collected in the environment of the hay fever sufferers using a handheld sniffer and the symptoms of these subjects.

Study design

This pilot study is designed as an observational, single center trial, with a total of 10 participants (n=10).

Visit 1:
* Informed consent: An Informed Consent will be obtained prior to subject*s participation. The subject will be given sufficient time to make an informed decision about participating in this trial.
* Anamnesis: (i) demographic data (ii) screening of their medical history (general and on allergy) (iii) medication use
* a general physical examination and a nasal examination to exclude chronically blocked nose
* Blood collection for the screening of specific IgE on inhalation allergens
Visit 2:
A joint meeting will be organized where the participants to the study will receive instructions on:
* How to use the pollensniffer
* How to change the samples in the sample holder

* The selection of the 2 weeks to measure the pollen and to score the symptoms; this selection will be made at the start of the grass pollen season and announced during the instruction meeting (or earlier if known).
* How to register symptom scores using the mobile application
* Subjects will be instructed not to use any medication for their allergic symptoms starting 3 days before the measurements until the last measurement. When this medication cessation leads to severe symptoms, the participants can contact the research team that will provide information on rescue medication. In this case the individual will have to leave the study.
Visit 3:
* Intake of the pollensamples and the pollensampler and completion of a questionnaire

Study burden and risks

The burden consists of one bloodsample, three site visits, physical examination, completion of a questionnaire. Furhtermore the partiicpants will have to collect pollen using the pollensniffer for two weeks during 15 min a day and score their symptoms.

The risk are estimated to be minimal.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Signed an informed consent consistent with ICH-GCP guidelines prior to participating in the trial;
* Male or female aged at least 16 years;
* Positive anamnesis of hay fever;
* Living in the region of Leiden in order to compare the results with the daily pollen counts of the LUMC.
* Positive specific IgE test for grass pollen

Exclusion criteria

* a clinically relevant pet allergy and the very pet at home;
* immunotherapy within 3 years prior to visit 1
* daily use of inhaled corticosteroids for asthma;
* daily use of oral corticosteroids;
* pregnant or breast feeding;
* chronically blocked nose;
* other significant disease (e.g. severe cardiovascular or pulmonary disease, malignancy, autoimmune diseases). Significant is defined as any disease that in the opinion of the investigator would put safety of the subject at risk through participation.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-04-2018
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	23-03-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	16-05-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL63953.058.17