Development of the basophil activation test.

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

Summary

ID

NL-OMON32817

Source
ToetsingOnline

Brief title
basophil activation test

Condition

- Allergic conditions
- Angioedema and urticaria

Synonym
anaphylaxis, fast allergic reaction, type 1 allergy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: farmaceutische industrie en eigen middelen van de afdeling allergologie,Schering-Plough

Intervention

Keyword: allergy, anaphylaxis, basophil activation test, small molecular substances

Outcome measures

Primary outcome

Reactors to the oral provocation test for diclofenac or to other allergy-tests

for subjects allergic to the other allergens are expected to have a greater

reaction to the basophil activation test than non-reactors.

Secondary outcome

n/a

Study description

Background summary

There are multiple tests available to diagnose an allergy. In Type-4 reactions epicutaneous patch-tests are used as well as the lymphocyte transformation test (LTT). In Type-1 reactions (immediate type reactions) mostly proteins function as allergens. Prick tests and in vitro determination of specific IgE are the tests of choice in these cases. There are however patients that have an immediate type allergic reaction to small molecular substances, which indicates that mast cells and basophils are involved. IgE involvement in these cases is not always clear. The basophils will degranulate through activation and histamine and other mediators are released. Because of this mechanism symptoms of an immediate (pseudo) allergic reaction occur. Identifying specific IgE is difficult in this situation, because the suspected substance has to be bound to a carrier. In prick tests and provocation challenges there is the risk of patient having an anaphylactic reaction. Therefore more diagnostic tests are desired.

The basophil activation test by flow cytometry is a recently developed test to mimic in vitro the contact between allergens and the cells responsile for symptoms (basophils and mastcells). By flow cytometry (FACS) it is possible to identify basophil in blood, even if a small number is available. With monoclonal antibodies to degranulation markers on the surface of the basophils, activation of the basophils can be detected. Multiple studies have demonstrated that the basophil activation test by flow cytometry is a reliable tool for

identifying degranulation markers on basophils by different allergens. By identifying the activation of basophils through the basophil activation test by flow cytometry, diagnosis and treatment of some patients will substantially improve.

Study objective

The aim of this study is to develop and validate the basophil activation test by flow cytometry in our hospital as an extra diagnostic procedure for patients, who can not be diagnosed with existing tests or who have the risk of developing anaphylaxis by performing diagnostic tests in vivo.

Study design

To validate the basophil activation test in our laboratory, birch pollen will be used as an allergen, because the basophil activation for this allergen is well documented. Subject non-allergic to birch pollen will serve as controls. As a second step the basophil activation test for diclofenac will be developed with patients with a positive oral provocation test to diclofenac in the last 3 years and subjects who tolerate diclofenac. Finally the basophil activation test for diclofenac will be developed for allergens from cosmetic substances, in particular benzophenone-3.
For this purpose 5 ml of blood will be needed from all subjects. The blood will be incubated with the allergen and with anti IgE as positive contol and activation buffer as negative control. Then antihuman IgE and CD63 and CD203c will be added. By flowcytometric analysis activated basophils will be isolated. The optimum concentration of the allergens will be searched to separate the allergic subjects from the non-allergic subjects.

Study burden and risks

The effort of patients will be kept to a minimum. Blood will be taken by experienced and qualified employees from the laboratory of the UMCG. The investment in time will be about 5 to 10 minutes per patient and will only include giving a blood sample. It will not be necessary to fill in questionnaires or any other forms.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Type 1 allergie for diclofenac, benzophenon-3 or birch pollen.

Exclusion criteria

Use of immunomodulatory medicine. Current infectious disease or fever.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	45
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL24239.042.08