

The application of buffy coats for histamine release assays.

Published: 23-01-2007

Last updated: 20-05-2024

The aim of the study is to determine the biological activity of specific IgE antibodies and allergens.

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

Summary

ID

NL-OMON30126

Source

ToetsingOnline

Brief title

Buffy coats application

Condition

- Allergic conditions

Synonym

Allergy, IgE mediated Type 1 hypersensitivity

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,HAL Allergenen Lab,HAL Allergenen Lab;Stallergenes,Stallergenes SA

Intervention

Keyword: basophil, buffy coat, histamin, sensitisation

Outcome measures

Primary outcome

Primary study parameters:

Titers specific IgE (as can be determined in RAST and CAP) do/do not correlate with histamin release when homologous allergens are applied.

The biological activity of a purified natural allergen does/does not correlate with a modified/recombinant allergen.

Secondary outcome

not available

Study description

Background summary

Buffy coats (i.e. basophils) are used to determine the biological activity of specific IgE antibodies and allergens. The histamin release assay is an elegant method which mimicks the allergic reaction, like it is taking place in the body, as natural as possible.

Study objective

The aim of the study is to determine the biological activity of specific IgE antibodies and allergens.

Study design

Healthy donors donate basophils which could be sensitized with IgE of allergic patients. Measurement of histamin after stimulating these basophils enables us the characterize the biological activity of IgE antibodies and/or allergen

Study burden and risks

The only risk for the donor is the donation of the buffy coat.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam Zuidoost
NL

Scientific

Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam Zuidoost
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Healthy male buffy coat donors without IgE sensitization. Hb levels >8.5 mmol/l are required.

Exclusion criteria

Buffy coat donors whose basophils show 1) a high spontaneous histamin release or 2) no histamin release after application of stimuli (non-responders).

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-06-2006

Enrollment: 5

Type: Anticipated

Ethics review

Approved WMO

Application type: First submission

Review commission: METC Amsterdam UMC

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

CCMO

ID

NL13018.018.06