Non-irritative concentrations for drug allergy skin tests

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Primary Objective: To determine for a series of drugs frequently used perioperatively the maximal non irritative concentration in intracutaneous skin testing in healthy volunteers.
Secondary Objective(s): To compare the percentage/number of positive...

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

Summary

ID

NL-OMON40331

Source
ToetsingOnline

Brief title
Drug allergy skin tests

Condition

- Allergic conditions

Synonym
drug allergy, drug hypersensitivity

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: drug allergy, intracutaneous skin test, skin test

Outcome measures

Primary outcome

The maximal concentration of drugs generally used in anaesthesiology that can

be used for intradermal skin tests without eliciting an aspecific (irritative)

response reaction.

Secondary outcome

The percentage/number of positive tests of each drug at each concentration as

judged by two different criteria (ENDA and SFAR).

Study description

Background summary

Over 7000 cases of immediate IgE-dependent hypersensitivity reactions caused by drugs used for anesthesia have been described in the last 25 years. These reactions can be diagnosed by intracutaneous tests with soluble drugs. However, not of all drugs is known which concentration can be used for intracutaneous testing without eliciting an aspecific (irritative) response. The absence of knowledge about these irritating or non-irritating concentrations limits the value of this diagnostic procedure.
Therefore, by performing standardised intracutaneous tests with increasing drug concentrations, this study aims at determining the maximum non-irritative test concentration of several drugs used in general anaesthesia.

Study objective

Primary Objective: To determine for a series of drugs frequently used perioperatively the maximal non irritative concentration in intracutaneous skin testing in healthy volunteers.
Secondary Objective(s): To compare the percentage/number of positive tests for each drug at each concentration between different scoring methods

Study design

Observational study with invasive measurements

Study burden and risks

The volunteers will visit the outpatient clinic 1-2 times for 1,5-2,5 hours (phase 1: 2 times max. 2,5 hour; phase 2: 1 time max. 1,5 hour). At the start of this visit the informed consent is signed. Subjects are tested for dermographism, and if negative, they will get 20 intradermal skin tests maximal set on their upper back.
The risk of severe reactions is minimized by excluding volunteers with a history of (drug) allergic reactions or atopy and by performing the skin test under close control in a place where all medication needed for treating a severe reaction is ready for use.

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

- absence of significant disease
- age * 18 year, * 50 year
- signed informed consent

Exclusion criteria

- Age < 18 year or > 50 year
- Previous general anaesthesia, with the exception of (adeno)tonsillectomie before 2000
- History of drug hypersensitivity
- History of anaphylaxis
- History of seasonal or perennial rhinoconjunctivitis
- Use of antihistamines, corticosteroids, immunosuppressant drugs
- Positive dermographism

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2013
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO Date:	01-02-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-07-2014
Application type:	Amendment
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	ID
CCMO	NL43023.018.12