The EDEN international study on the prevalence of contact allergy to fragrances

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To test the feasibility of an intended large scale fragrance-allergy prevalence study in the population of the north of the Netherlands and to make a more reliable estimate of the prevalence in the population for poweranalysis of the intended large...

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON29931

Source
ToetsingOnline

Brief title
Eden-Ifra prevalence study

Condition

- Skin and subcutaneous tissue disorders NEC

Synonym
allergic skin reaction, irritation of the skin

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: pharmaceutische industrie

Intervention

Keyword: allergic contact dermatitis, fragrances, hypersensitivity, perfume

Outcome measures

Primary outcome

Oversenstivenessreaction of the skin and presence of NAT-1 en NAT-2 (fast en

slow acetylators) in the blood.

Secondary outcome

n.v.t.

Study description

Background summary

Fragrances or perfumes are part of cosmetics according to a European definition. They are constantly present in our environment and in products which we daily use, like soap, lotions and shampoos. Therefore its not surprising that fragance is becoming more prevalent as a form of contactdermatitis. Contactdermatitis is an infection which leads to a red skin, itch, and swelling of the skin which can cause severe limitations in daily living. The symptoms appear mostly in the face, the eylids, neck, arm-pits and groins.

Study objective

To test the feasibility of an intended large scale fragrance-allergy prevalence study in the population of the north of the Netherlands and to make a more reliable estimate of the prevalence in the population for poweranalysis of the intended large scale study.

Study design

A questionnaire has been developed by the EDEN group and was tested for reliability in a prepilot-study. The questionnaire can approximately define whether a person has had an allergic reaction of the skin which can be ascribed to cosmetics and/or fragrances. Persons with a positive outcome on the questionnaire (cases), which means that they are possibly allergic to cosmetics/fragrances will be asked (cases) to cooperate on a patch-test

procedure to validate the questionnaire and to define the algorithm and to a blood test to define the over-senstiviness for hair cosmetics. The same will be asked to a at random selected number of persons with a negative outcome (controls).

Study burden and risks

The time-estimate for completing the questionnaire is at most twenty minutes. Cooperation in the patch-test procedure contains the following. The patch-test will be fixed on the respondents back for two days. The respondent will be hindered by the patch-test if the patch-test is abundantly contacted with water. Showering therefore has to be done with a hand shower. The patchtest will be removed after two days, and the day after (day three) it has to be read at the out-patient department of the UMCG. Removal of the patch-test will be done by the same person who filled out the questionnaire in a place which is choosen by the respondent. Five milliliters of blood will be taken at the moment the respondent comes to the out-patient clinic and if positive permission is given beforehand.

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

age 18-75 years old, Dutch speaking, able to gibve informed consent

Exclusion criteria

not known with an active skin disorder

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):	01-09-2006
Enrollment:	100
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	NL13475.042.06