Fragrance allergy and skin tolerability to essential oils

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Primary Objective: What is the frequency of positive patch test reactions to the 26 declarable fragrance allergens in fragrance mix I and/or II positive participants?Secondary Objectives: Do Weleda cosmetic products containing essential oils,...

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

Summary

ID

NL-OMON32295

Source
ToetsingOnline

Brief title
'Fragrance study'

Condition

- Allergic conditions
- Epidermal and dermal conditions

Synonym
Allergic contact dermatitis to fragrances

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Bedrijven

Intervention

Keyword: Contact dermatitis, Fragrance, Skin

Outcome measures

Primary outcome

The primary study parameters are reactions regarding the ICDRG guidelines on

patchtests, skin irritability tests and a repeated open application test (user

test).

Secondary outcome

not applicable.

Study description

Background summary

Contact dermatitis (CD) is an inflammatory response of the skin to an irritant or allergen that has direct skin contact. Reactions to an irritant can cause irritant contact dermatitis by a non-immunological pathway in which direct damage is done to epidermal keratinocytes .(1) In contrast, allergic contact dermatitis (ACD) is an allergen-specific T-cell mediated immune response in readily sensitized individuals. ACD consists of a type IV hypersensitivity response to an allergen (also called hapten) that pathologically can be divided in two phases: the sensitization (induction) phase and the elicitation (effector) phase. In the sensitization phase the first immunologically relevant contact with the allergen occurs. In general, this is clinically not visible on the skin and remains unknown to the patient. But, ACD reactions will occur upon renewed contact to the specific allergen. This eczematous reaction is the clinical manifestation of the elicitation phase. (2)
Fragrance allergy occurs approximately in 1-2% of the general population and is, thus, one of most frequent contact allergens. (3-5) When a patient is diagnosed with a fragrance allergy, the principal advice is to avoid contact with all fragrances and potentially cross-reacting or concomitant substances. (6;7) However in general, sensitization is limited to few fragrance allergens only. Hence, if a patient would know to which fragrance allergen (s)he is sensitized to, a specific advise on avoidance and safe alternatives can be given. Identification of the most frequent sensitizers among fragrances and of concomitancy between individual fragrances is of important clinical relevance

needed for adequate patient advices.
A group of commercially important fragrances are essential oils. Essential oils contain various fragrances at different concentrations. (8) There are indications that fragrance allergens in distinct combinations provoke less allergic reactions than fragrances tested separately. (9) Since essential oils contain various fragrances, they might show lower allergenic potentials than the respective fragrance ingredients tested separately. Moreover, essential oils contain antioxidants which may also reduce allergenicity.
This study therefore has the aim to improve clinical diagnostics and treatment of fragrance allergic patients.

REFERENCES

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Study objective

Primary Objective:
What is the frequency of positive patch test reactions to the 26 declarable fragrance allergens in fragrance mix I and/or II positive participants?

Secondary Objectives:
Do Weleda cosmetic products containing essential oils, provoke allergic contact dermatitis skin reactions in fragrance mix I and/or II positive participants?
Does increment of concentration of essential oils in Weleda cosmetic products, still below concentrations used in commercial patch test material, provoke more patch test reactions than the original product?

Do concomitant patch test reactions occur among fragrance allergens?
If applicable, which concomitant reaction patterns are significant?
Do eugenol containing essential oils provoke less contact allergy than eugenol, tested solitary in the same concentration?
Does supplementation of the antioxidant Vitamin E to eugenol reduce skin test reactivity to eugenol?
Do participants, who react to Weleda cosmetic products, have increased skin irritability in comparison to participants non-reacting to Weleda cosmetic products?

Study design

Mono-center double blind prospective volunteer study.

Intervention

All participants are offered patch tests, a skin irritability test and a repeated open application test (user test) with (components of) cosmetics.

Study burden and risks

Participants have to invest time to come to the dermatology outpatient clinic (5 visits, each of approximately 30 minuts). (Minor) discomforts can occur from the patch tests, skin irritability test and repeated open application test. For example local itching, redness of the skin, sometimes with vesicles, can occur. The study procedures are routine procedures in dermatological diagnostics. The substances to be tested in this study are either routine diagnostic substances or commercially available cosmetic products or a combination of them. These substances have to remain attached to the skin and therefore the skin of the back and arm should not be showered during the first visit 1 until visit 3 of the study. Sporting should also be avoided. After visit 3 we will ask not to sport and wet the back and the arm during showers. Light showers are permitted. Participants could benefit from the additional advice they receive about their allergy. They will have gained more specific information about their allergy, substances to which they have to avoid skin contact to and, if possible, safe alternatives for cosmetic products.

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

Diagnosed contact allergy to fragrance (mix I and/or II) with a positive patch test (+, ++ or +++ interpreted according to the ICDRG guidelines)
Clinical healthy skin of the back in two preceding weeks
Written informed consent

Exclusion criteria

Pregnancy or lactation
Age under 18 or above 70
Legally incompetent adults
Topical treatment of immunosuppressives on the back and arms within 7 days before performing patch tests and until finalization
Commercial skin lotions and ointments on the back and arms less than 8 hours before patch testing
Extensive UV exposure of the back and arms in the last 14 days before performing patch tests and until finalization
Usage of systemic immunosuppressive drugs (e.g. prednison, acitretine, adalimumab, efalizumab, etanercept, methoxsaleen, cyclosporine, azathioprine, infliximab and methothrexate)

NB: Medication that reasonably not intervenes with the study procedures (e.g. an antihistaminicum can be used during the study)
Severe illness, defined as life threatening or severely disabling

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2008
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	04-06-2008
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	ID
CCMO	NL21944.029.08