Validation of a questionnaire algorithm for 'allergic contact dermatitis' with the Repeated Open Application Test (ROAT) for fragrances.

Published: 22-10-2013
Last updated: 23-04-2024

The aim is to validate the hypothesis that a positive history defined as dermatitis at exposure to a scented product and thereafter avoidance of such products in fragrance-hypersensitive individuals and a positive patch test result to fragrances is...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Observational invasive

Summary

ID

NL-OMON38649

Source
ToetsingOnline

Brief title
Validation of a questionnaire algorithm for 'allergic contact dermatitis'

Condition

- Epidermal and dermal conditions

Synonym
allergic contact dermatitis, Contact allergy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W,GISED (Gruppo Italiano Studi Epidemiologici in Dermatologia)

Intervention

Keyword: Allergic Contact dermatitis, Contact allergy, Fragrance mix, Repeated Open Application Test

Outcome measures

Primary outcome

The primary study result is the level of agreement between the result of the ROAT and the questionnaire algorithm (combination of patch test result and questionnaire), both defined as a dichotomous variable: POSITIVE or NEGATIVE

Minimal criteria for a positive ROAT are the presence of erythema and infiltration in the same area and possibly papules and vesicles in affected area and covering at least 25% of the area of application.

Secondary outcome

Other parameters are:

- The result of the patch test: The presence or absence of a positive reaction at day 3 or day 7 at the skin site where the patch has been applied. Reading of the reaction will be according to the criteria of the ICDRG, whereby 'positive' includes a + , a ++ or a +++ reading.

- The result of the ROAT whereby the minimal criteria for a positive ROAT are the presence of erythema and infiltration in the same area and possibly papules and vesicles in affected area and covering at least 25% of the area of

application.

- Negative

- Doubtful Erythema and/or

infiltration/papules/vesicles not fulfilling the minimal criteria for a

positive reaction.

- Weakly pos 25-50% coverage with erythema and infiltration

in the same area and possibly papules and few vesicles

- Moderately positive > 50% coverage with erythema and infiltration in the

same area and possibly papules and few vesicles

- Strongly positive > 50% coverage with erythema and infiltration in

the same area and possibly papules and at lest 10-25 vesicles

- the result of the algorithm of the questionnaire

- combination of the above mentoined factors.

Study description

Background summary

Unlike for dermatoses such as psoriasis and atopic dermatitis, there are no criteria of universal acceptance to establish the diagnosis of "allergic contact dermatitis" based on questionnaire answers.
In the EDEN fragrance study, recently conducted in Europe on contact allergy in the general population, it was hypothesized that the combination of contact allergy to a fragrance test preparation at patch testing together with a history indicating dermatitis at exposure and thereafter subsequent avoidance of scented products implied a diagnosis of allergic contact dermatitis.
However, this algorithm is not validated.

A Repeated Open Application Test (ROAT) is a simple method to investigate whether someone is allergic to a specific allergen and it is considered as the golden standard for the diagnosis *allergic contact dermatitis*. The majority of the ROAT can easily be performed by the test subject at home, although it is a time-consuming method, given the fact that the ROAT may take up to 28 days.

This study will re-investigate a part of the subjects of the EDEN fragrance study to validate the questionnaire algorithm and to investigate whether a positive history and a positive patch test are comparable to the diagnosis of "allergic contact dermatitis" proven by a ROAT

Study objective

The aim is to validate the hypothesis that a positive history defined as dermatitis at exposure to a scented product and thereafter avoidance of such products in fragrance-hypersensitive individuals and a positive patch test result to fragrances is equivalent with the diagnosis "allergic contact dermatitis" diagnosed by a ROAT.

Study design

A multicenter, randomized study with healthy volunteers from the general population and blinded observers.

3 groups of subjects from the EDEN fragrance project will take part in this study.

A: 40 individuals hypersensitive to fragrance mix I (FM I), 20 with and 20 without a positive history
B: 40 individuals hypersensitive to fragrance mix II (FM II), 20 with and 20 without a positive history
C: 40 individuals without contact allergy to FM I, FM II, ingredients of FMs and Myroxylon pereirae, 20 with and 20 without a positive history.
In Groningen we will include 20 subjects, 6 subjects with FM I, 5 with FM II and 9 individuals for the control group.

A positive reaction at ROAT will be used as a proxy for allergic contact dermatitis. 4 test solutions will be used, all using ethanol/DEP 98/2 v/v as vehicle.

a. ROAT solution with FM I ingredients at highest possible concentrations
b. ROAT solution with FM II ingredients at highest possible concentrations
c. ROAT solution - only vehicle
d. Control (no application)

The ROAT solutions will be applied twice daily for 4 weeks on the volar aspects

of the lower arms, 2 solutions on each arm, according to a Latin square table. 4 areas of each 3x3 cm will be used (of which one will be left untreated). The dose applied each time is 2 drops from a special bottle which gives approximately 50µl.

The ROAT test areas will be scored once a week. To be considered a positive ROAT, at least 25% of the test area must be erythematous with infiltration and/or papules.

When starting the ROAT all subjects will be patch tested using the Finn Chamber technique with small chambers, diameter 8 mm. The ROAT solutions and the 2 FMs will be tested.
15 µl of solutions and 20mg of petrolatum preparations will be applied on the chambers which will be applied on the back under occlusion for 48 hours (regular patch test protocol). The test will be scored according to ICDRG on 2 occasions, day 3 and day 7

Study burden and risks

The burden for participants will be kept to a minimum. Application of the patch test or the ROAT solution is not painful or discomfort able, although this study is quit time-consuming for participants.

The subject will visit the UMCG 6 times on day 0, 3, 7, 14, 21 and day 28. The first visit will take 40 minutes; the remaining visits will take about 15 minutes each. The time-consuming part of this study is the application of the ROAT solutions. After application, the ROAT solutions need to dry to air, which takes about 10 minutes. Applying ROAT to two arms, twice a day, results in an investment of 40 minutes a day during 28 days.

Perfume allergic people are expected to get an itchy dermatitis as an expression of a positive allergy test and ROAT. Such eczema is transient and usually disappears without action within days. If unexpected strong dermatitis reactions occur, corticosteroid cream can be administered and alleviate symptoms.
For individuals who are not allergic all skin contact with potential sensitizers poses a risk for sensitization. Concentrations of the test preparations used for the patch testing are the ones used all over the world and no documentation on sensitization is present. Concentrations of the fragrances in the ROAT solutions are significantly lower and also of the same magnitude as in other scented products that the research subjects probably use daily, e.g. in deodorants, after shave, toothpaste, soap and shampoo.

Subjects will receive reimursement of the travel expenses and a VVV-bon with a value of ¤225,- after completion of the study, or a part of this after drop-out.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria for the Fragrance Mix positive subjects:
- Participated in the EDEN fragrance study and gave permission to be re-invited for a follow-up study
- Positive patch-test to FM I and/or FM II
- Adulthood (18 years and older)
- Legal competent
- Understands Dutch;Inclusion criteria for the FM-negative subjects (controls):
- Participation in the EDEN fragrance study and gave permission to be re-invited for follow-up studies
- Negative patch test results to all fragrances including fragrance mix I and fragrance mix II
- Matched to the FM-positive group for age and gender
- Adulthood (18 years of age or older)

- Legal competence
- Understands Dutch

Exclusion criteria

Exclusion criteria for both groups are:
- Skin anomalies on the forearms and back such as active eczema
- Immunosuppressive medication during the study or in the four weeks before inclusion (oral corticosteroids, cyclosporine, methotrexate, azathioprine, biologicals)
- Pregnancy (wish)
- Legally incompetent
- Difficulty understanding oral and written information in Dutch.
- Angry back in the past (extreme hypersensitivity to pacth test resulting in a red, itching back or multiple false-positive patch test reactions)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	22-10-2013
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	NL44777.042.13