Range-Finding and Pilot Study For: Extended Fragrance Ingredients Surveillance Study (EFISS) - Surveillance Study to Monitor the Frequency of Contact Allergy to a Defined Group of Fragrance Ingredients with a View to Providing Reliable Information on Trends

Published: 25-11-2020
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To design an industry-sponsored surveillance study incorporating both additional and existing materials that has the possibility of identifying trends in the incidence of skin contact allergy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Administration site reactions
Study type	Observational invasive

Summary

ID

NL-OMON49753

Source
ToetsingOnline

Brief title
Pilot study: Extended Fragrance Ingredients Surveillance Study (EFISS)

Condition

- Administration site reactions
- Allergic conditions
- Epidermal and dermal conditions

Synonym

allergic contact dermatitis, contact eczema

Research involving
Human

Sponsors and support

Primary sponsor: The International Fragrance Association (IFRA)
Source(s) of monetary or material Support: Parfum indrustrie,The International Fragrance Association (IFRA)

Intervention

Keyword: Allergic contact dermatitis, Epicutaneous patch-testing, Fragrance ingredients, Pilot study

Outcome measures

Primary outcome

The results of the epicutaneous patch tests for the different concentrations of

the fragrance materials according to the guidelines of the International

Contact Dermatitis Research Group (ICDRG)

Secondary outcome

• Gain familiarisation with the additional materials

• Test quality procedures designed to address intra- and inter centre variations

• Test the CRF (Case Report Form: See Annex VI) and its administration

Study description

Background summary

Fragrance-induced skin contact allergy has been identified as being of high concern. The IDEA project is designed to provide a broadly agreed and transparent framework for assessing fragrance sensitizers globally. A key issue for successful monitoring in trends has been that testing has relied on a set of patch test substances, i.e., Fragrance Mix 1 and Fragrance Mix 2 (FM 1 and FM 2) that have remained essentially unchanged for over 35 and 15 years respectively with no additional materials being added. There are number of

materials of varying potency which hitherto have not been tested on a systematic basis, which are in use in product types with high consumer exposure.

Study objective

To design an industry-sponsored surveillance study incorporating both additional and existing materials that has the possibility of identifying trends in the incidence of skin contact allergy.

Study design

Study design:
Observational, non-invasive pilot study with the application of additional epicutaneous patch test series on the back. Without the use of medicinal product, non-blinded and non- randomized.

Duration:
The duration for an individual participant is one week during which there will be three visits of variable time durations. The visits are already scheduled because of scheduled diagnostic work-up.

Visit 1, day 0:
A short interview will be held to reconfirm basic information about the subject and to check the inclusion and exclusion criteria. Informed consent will be signed. This visit also includes the preparation of material, the application of the patch test on the back. This visit will take about 30 minutes. The actual patch test needs to be in situ for 48 hours.

Visit 2, day 3, 72 hours after application:
The visit will take about 15 minutes and includes reading and photographing of the (possible) skin reactions at the sites of application.

Visit 3, day 7, 168 hours after application:
This visit includes the final reading and photographing of the (possible) skin reaction at the sites of applications and will take about 15 minutes.

Study burden and risks

It is important to note that included subjects are already scheduled for routine diagnostic patch test investigation because of dermatitis. Therefore, subject do not have to schedule additional visits for study participation. For the routine diagnostic patch test investigation three visits will be planned. The first visit will take approximately 30 minutes and the remaining visits will take 15 minutes each. At first visit, after inclusion, subjects will be

asked to answer questions concerning medical history and concomitant medication. Subjects are at risk for developing an allergic skin reaction on the test sites. This skin reaction is self-limiting in nature, but can be treated with a local corticosteroid cream if the reaction is inconvenient.

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

- Adulthood (>=18 years); 4 weeks before the day of application of the patch test
- Legal competence

Exclusion criteria

- Patients who have had topical steroids applied to their back less than 7 days before the application of the patch test.
- Active skin disease or skin anomalies on the back
- Immunosuppressive medication (e.g. oral cortosteroïds, methotrexate, cyclosporine)
during or in the previous 4 weeks of the study;
- pregnancy or breastfeeding

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):	21-04-2022
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	25-11-2020
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	NL73107.042.20