

EDEN international study on the prevalence of contact allergy to fragrances

Published: 18-02-2009

Last updated: 06-05-2024

To estimate the one year-prevalence of contact allergy to fragrance ingredients in the general population of six different geographical areas in Europe spread over five different countries

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

Summary

ID

NL-OMON32711

Source

ToetsingOnline

Brief title

EDEN-FS

Condition

- Epidermal and dermal conditions

Synonym

contact dermatitis, rash from cosmetics

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Research Institute for Fragrance Materials (RIFM) en RIVM/VWA

Intervention

Keyword: contactallergy, fragrances, prevalence

Outcome measures

Primary outcome

The number of participants in the study with one or more positive reactions on the patchtest.

Secondary outcome

The number of participants in the study with a confirmative answer on question 1 of the clinical part of the EDEN questionnaire (monthprevalence).

The number of participants in the study with a confirmative answer on question 2 of the clinical part of the EDEN questionnaire (one-yearprevalence).

Study description

Background summary

Data originating from allergology services concerning what is known as *patch test population* suggest that the frequency of allergies to fragrances is continuously increasing. Given the widespread use of substances with fragrance content (detergents, shampoos, deodorants etc) by the general population, it is understandable how this increase may be relevant with regard to public health. Epidemiology can provide a crucial contribution in evaluating the importance of allergy to fragrances, estimating the frequency of the disease within the population and assessing the role of potential risk factors.

Study objective

To estimate the one year-prevalence of contact allergy to fragrance ingredients in the general population of six different geographical areas in Europe spread over five different countries

Study design

The study design of EDEN-FS is quantatative cross-sectional

Study burden and risks

The patchtestprocedure has been administered on a large scale for many decennia. Adverse reactions or health risks are not known to the patchtest procedure. The only burden to the participant is that he/she has to avoid contact with water in the places on the skin where the patches are attached (the back).

Contacts

Public

Universitair Medisch Centrum Groningen

a deusinglaan 1, postbus 196
9700 AD Groningen
NL

Scientific

Universitair Medisch Centrum Groningen

a deusinglaan 1, postbus 196
9700 AD Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

age 18 to 74 years

Exclusion criteria

- persons who cannot speak or write the native language
- persons who are unable to give informed consent
- persons with an active skindisease

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 22-07-2019

Enrollment: 2000

Type: Actual

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	NL24608.042.08