Explorative study: the relevance of contact allergy to isobornyl acrylate in people with an other acrylate allergy

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The objective of this study is to find out the relevance of adding isobornyl acrylate to the (meth) acrylate. Sub question: What is the relevant test concentration of isobornyl acrylate?

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

Summary

ID

NL-OMON35745

Source
ToetsingOnline

Brief title
Relevance of isobornyl acrylate allergy

Condition

- Epidermal and dermal conditions

Synonym
allergic contact dermatitis, contact eczema

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: acrylate, contact allergy, Isobornyl acrylate (IBA)

Outcome measures

Primary outcome

The primary study parameters are the results of the patch tests. These will be scored following the guidelines of the International Contact Dermatitis Research Group (ICDRG).The responses are qualified as -, +? , +, ++, +++ or IR (irritation) response. The +, ++ and +++ will be translate in 1 and relevant for our study, while -, +? and IR will be translated into 0 and will be considered negative.

Besides the scores, we will also take pictures of the back.

Secondary outcome

n.a.

Study description

Background summary

The reason for this study is a 48 year old man who suffered of a therapy-resistant hand eczema for nine months. He was working as a process operator in a factory producing glass fibers. The patient was occupied with the process of UV-painting of glass fibers, printing the glass fibers, covering it with acrylate and cleaning the machines. His skin problems diminished considerably during holidays and complaints returned as soon as he got back to work at the factory. The patient was examined with the European Standard series of the Epicutane allergy test (ECAT) and with ECAT (Meth) acrylate series. Altough the patient did not react to the European Standard series, he responded positively to many (meth) acrylates such as ethyl acrylate, butyl acrylate, 2-hydroxyethyl acrylate, 2-hydroxypropyl acrylate, 2-hydroxyethyl methacrylate, 2-hydroxypropyl methacrylate, triethylene glycol dimethacrylate, 1,6-hexanediol diacrylate, diethyleneglycol diacrylate, triethylene glycol diacrylate. However, these acrylates did not appear to be relevant for his complaints,

because these components did not occur in the substances with which our patient was working with. After further analyzing his working area, isobornyl acrylate appeared to be a component of the glass fiber coating, the Bufferlite and UV-inkt. A new ECAT with isobornyl acrylate 0.1% showed a strong positive allergic reaction.
Isobornyl acrylate is a substance which does not occur in the (meth)acyrlate series. This patient and his positive reaction to isobornyl acrylate as well as his positive responses to non-relevant acrylates create the base for this study.
Cross reactions between acrylates have been known since 1977. Chung et all (1) described this with search on guinea-pigs. A review from 2001 (2) described that several hypotheses exist on cross responses depending on additive groups of the monomeer and in vivo responses. However, this review doesn't mention isobornyl acrylate. In today's literature little is known about isobornyl acrylate. There are only four research groups which have specifically occupied themselves with isobornyl acrylate. The studies which have been performed in the past, rarely show an allergic response to isobornyl acrylate.
Kiec-Swierczynska et all (3) studied a group of 81 employees from a video/television factory who were working with isobornyl acrylate 0.1%. None of the employees showed a positive reaction to isobornyl acrylate. Aalto-Korte (4) performed a few studies on isobornyl acrylate. In a retrospective research 49 patients were suspected of having a labour-related contact dermatitis, while none of them reacted to isobornyl acrylate 0.1%. Busschots et al (5) found two patients with a relevant contact allergy for isobornyl by using an insulin pump.

Hypothesis: Patients who have tested positively for any of the substances in the (meth) acrylate series in the past, can also have allergic reactions to isobornyl acrylate. Patients who have reacted in the past to several acrylates or to acrylates which are chemically more similair to the structure of isobornyl acrylate are probably more likely to respond to isobornyl acrylate.

References:
1. Chung CW, Giles AL. Sensitization potentials of methyl, ethyl, and n-butly methacrylates and mutual cross-sensitivity in guinea pigs. The journal of investigative dermatology April 1977
2.Kanerva L. Cross-reactions of multifunctional methacrylates and acrylates. Acta Odontol Scand 2001; 59:320-329. Oslo. ISSN 0001-6357.
3.Marta Kiec-Swierczynska, Beata Krecisz, Dominika Swierczynska-Machura, Joanna Zaremba An epidemic of occupational contact dermatitis from an acrylic glue. Contact Dermatitis. 2005 Mar;52(3):121-5.
4.Kristiina Aalto-Korte, Maj-Len Henriks-Eckerman, Outi Kuuliala, Riitta Jolanki, Occupational methacrylate and acrylate allergy - cross-reactions and possible screening allergens Contact Dermatitis. 2010 Dec;63(6):301-12. doi: 10.1111/j.1600-0536.2010.01760.x.
5.Busschots A M, Meuleman V, Poesen N, Dooms-Goossens A. Contact allergy to components of glue in insulin pump infusion sets. Contact Dermatitis 1995: 33:

205-206.

Study objective

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Sub question: What is the relevant test concentration of isobornyl acrylate?

Study design

Participants to this study will undergo epicutane patchtesting according to the protocol of the International Contact Dermatitis Research Group. The patchtest exists of the (meth)acrylate series of the UMCG and a van der Bend Chamber filled with isobornyl acrylate (IBA) in petrolatum in different concentrations. IBA will be tested in concentrations varying from 0.3%, 0.1%, 0.03%, and 0.01%. The patchtest will be applied onto the back and must stay in situ for 48 hours. After 48 hours the patchtest will be removed and the first reading will be performed. The patchtest will be read again after 72 hours. During the readings we will use the guidelines of the International Contact Dermatitis Research Group (ICDRG). The results will be graded as -, +? , +, ++, +++ or IR (irritated) response. The results +, ++ and +++ are relevant for our study. We will also take pictures of the participant's back.

References:
Contact Dermatitis 5th edition, Springer 2010, Jeanne Duus Johansen, Peter J. Frosch, Jean-Pierre Lepoittevin
Fregert S. Publication of allergens. Contact Dermatitis 1985;12:123-124

Study burden and risks

The burden for the participants in this research will exist of the following:
- Before participation: exclusion of possible pregnancy, use of immunosuppresive drugs and active skin disease on the back, which will be followed by inspection of the back for exclusion of any active skin diseases by menas of a questionnaire
- Four visits to the UMCG or house visits spread over one week. A visit lasts 15 minutes on average.
- The real burden exists of the application of the patch test on the back for 48 hours. The participant ought te keep the application site dry during one week.
- Afterwards a second questionnaire will be used to manifest a possible exposure to acrylates and isobornyl acrylate in particular.

Risks
- Irritation and itching on the site of the patchtest. To minimalizes these risks hypoallergic bandages are used. Possible irritation or itching will

disappear spontaneously after removing the patcht test.
- Small risk of active sensibilization for isobornyl acrylate.

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
- Legal competence
- Epicutanous skin test in the UMCG between 01-01-2000 and 01-02-2012
- Positive reaction (at least +) for at least one acrylate

Exclusion criteria

- Legally incompetence
- Angry back in the past
- Active skin disease on the back
- Use of immunosuppresive drugs
- Pregnancy(wish)

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):	01-09-2011
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-11-2011
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	NL36823.042.11