The Allergy Alert Test, a proof of concept study

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

Summary

ID

NL-OMON38497

Source
ToetsingOnline

Brief title
AAT-POC

Condition

- Epidermal and dermal conditions

Synonym
Allergic contact dermatitis, contact eczema

Research involving
Human

Sponsors and support

Primary sponsor: L'Oréal
Source(s) of monetary or material Support: L'Oréal

Intervention

Keyword: Allergic contact dermatitis, Allergy Alert Test, Epicutaneous patch-testing, Para-phenylenediamine (PPD)

Outcome measures

Primary outcome

The result of the Skin Self Test, read by a dermatologist.

The reaction will be scored according to a strict protocol: negative (-),

positive (+, ++ or +++), irritant (IR) or doubtful (?) reaction, for which all

positive reactions will be considered as POSITIVE, whereas the doubtful,

negative and irritant reactions will be considered as NEGATIVE.

Secondary outcome

- The result of the Skin Self Test, interpretated by the study subject. Graded

negative (no reaction at all) or positive (some kind of reaction)

- Agreement between independent test evaluations of the dermatologist and the

study subject.

- The result of the Skin Self Test graded by the dermatologist scored as

negative (-), positive (+, ++ or +++), irritant (IR) or doubtful (?) reaction

The influence of:

- Product applied: hair colouring formula mixed with developer (in use ratio)

- Reading time:

a) dermatological evaluation at 15 - 20 minutes after test removal, Day 2,

Day 4 and later if considered necessary

b) independent daily self-evaluation by subjects: 15 - 20 minutes after test

removal, Day 1, Day 2, Day 3 Day 4 and later if neces-sary.

- Site: retro-auricular region versus volar aspect of forearms

Study description

Background summary

p-Phenylenediamine (PPD) is an important primary intermediate with a long history of extensive use in oxidative hair colourants. PPD is a well-known allergen and occlusive patch testing to PPD in the standard series have been used for many years in dermatological practice to establish diagnosis of contact allergy. Between 4 and 7% of the patch tested population is sensitized to PPD. PTD is another component in oxidative hair colourants, which might cause contact allergies.
In order to avoid the manifestation of contact dermatitis elicited by the hair-dyeing procedure, hair dye manufacturers recommend an "allergy alert test" or "skin self test" (skin sensitivity test, consumer open test) with the hair colourant formulation, before hair colouring. This open test consists in the application of the hair colourant to the skin for a defined period of time followed by a reading 48 hours later. It should alert the hair colourant user not to apply the product when experiencing any sensory or physically noticeable deviation from normal conditions and to seek medical advice.

The effectiveness of 3 different alert test protocols was evaluated in preceding studies carried out under dermatological control both with PPD containing (1-3) and PTD-containing products (4).
During an EU workshop in April 2011, various aspects of the skin self test protocol were discussed. It was recommended to harmonize the test protocol across companies and that exposure time and test preparation used (colorant formula mixed with developer) should reflect the actual use conditions. Furthermore it should be ensured that the consumer can perform and understand the potential alert signs of the test. More recently a population study reported an adequate validity of self-testing for nickel allergy showing that in most cases consumers are able to understand and correctly interpret alert signs from self tests (5).
This study is a first step in the validity of skin self test for hairdyes, therefore this proof of concept study will be carried out.

Study objective

The study will be designed as a multicenter study to evaluate the impact of several parameters influencing the sensitivity and specificity of skin self tests.

The parameters are:
- Product applied: hair colouring formula mixed with developer (in use ratio)
- Reading time:
a) dermatological evaluation at 15 - 20 minutes after test removal, Day 2, Day 4 and later if considered necessary
b) independent daily self-evaluation by subjects: 15 - 20 minutes after test removal, D1, D2, D3 D4 and later if necessary.
- Site: retro-auricular region versus volar aspect of forearms

Patients with a history of allergic reactions to hair dyes and a proven allergy to PPD will carry out the skin self test with hair dyes containing different concentrations of PPD corresponding to light, medium and dark shades of hair colourants.
Positive results to the skin self test by dermatological evaluation or self-evaluation will be validated against a defined *gold standard* for hair dye allergy: the elicitation of clinical manifestations of allergic contact dermatitis by the application of a particular hair dye product in real life conditions. Sensitivity and specificity of the alert test will be evaluated using this gold standard.

In addition, test site evaluations by dermatologists and by study subjects, carried out independently, will be compared.

Study design

Observational study with the use of epicutaneous Skin Self Test and without the use of a medicinal product.

Study burden and risks

No serious adverse events are expected during and after patch-testing. This thought is supported by senior-researcher M. Krasteva MD PhD (see K6 safety and risk assessment)
On the day of the patch-test application the time burden will be 90 minutes at the most, in addition to travel time to the clinic. The actual application of the patch will cause no harm or discomfort. The time burden for reading the patch test reaction will be less than 15 minutes.
The total time burden on subjects depends on the reactions to each individual test cycle. If a subjects reacts to a low dose PPD, the time burden is only one cycles. Is someone does only reacts to a high dose of PPD, all the four cycles will be completed.

It is anticipated that the majority of the PPD-sensitive subjects will develop redness, possibly with some itching, at the site of the patch-test with the PPD containing solution. This redness is transient, and will disappear within a few days without leaving scars. Participants have the option to receive a one-time

application of a corticosteroid-containing cream to enhance the remission of the reaction. Systemic effects from resorption of PPD are irrelevant at such a short exposure time and small application area.

Subjects do not directly benefit from partcipation in this study.

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

Study subjects with PPD sensitization:
• Males and females, 18-65 years of age;
• Consecutively patch tested patients, who have shown positive reactions to PPD (+, ++ and +++) within the last 5 years included in the database of the department Dermatology;
• Clinical relevance of the positive patch test reaction: self-declared past exposure to

oxidation hair dyes and clinical manifestations compatible with contact sensitivity to hair dyes (documented in CRF). All patients will be required to provide information on the approximate shade (light, medium or dark) responsible for their reaction.
• Healthy skin on the test site for at least 3 months on entering the study;
• Legal competent;PPD-negative subject must meet all of the following criteria:
• Consecutively patch tested patients, males and females, oxidative hair dye consumers, 18-65 years of age, who have shown negative reactions to PPD and to all other tested allergens with the exception of nickel (tests carried out 12 months to 3 weeks before inclusion into the study);
• Sex and age-matched (within 5 years), whenever possible, to test subjects;
• No history of adverse reactions to hair colouring products;
• Healthy skin on the test site for at least 3 months;
• Legal competent

Exclusion criteria

Exclusion criteria:
• Hairdressers; current or past occupation
• Current acute or widespread eczema at any site, any eczema on the test sites within the last 3 months before study;
• Significant past medical history which in the opinion of the investigator can interfere with the study;
• Febrile illness lasting more than 24 hours in the six days prior to each patch application;
• Past or concomitant medication likely to affect the response to the test articles or confuse the results of the study (systemic treatment: corticosteroid or immunosuppressive 1 month prior and during the study);
• Recent vaccination (less than 3 weeks prior to patch application);
• Insulin-dependent diabetes;
• Recent history of extensive sun exposure;
• Deliberate exposure of the test sites to natural sunlight or artificial sources of UV light in the two weeks preceding the study, during the study, and during the two weeks following the study;
• Participation in a diagnostic patch test during the six preceding weeks for PPD-positive subjects and during the three preceding weeks for PPD-negative subjects;
• Pregnancy or breast feeding or active childwish

Study design

Design

Study type:	Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2014
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Open application test / Allergy Alert test
Registration:	No

Ethics review

Approved WMO

Date:	03-06-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	29-04-2016
Application type:	Amendment
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	NL45084.042.13