Pilot-study of a simple allergy self-test in persons who have had a skin-reaction to PPD containing hair dye.

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A pilot-study to the feasibility of a simple self-patchtest with a PPD containing hair-dye solution. The aim is to investigate whether a 30-minutes application of a patch-test gives a positive reaction in individuals who have a proven contact...

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

Summary

ID

NL-OMON31947

Source
ToetsingOnline

Brief title
PPD allergy self-test pilot

Condition

- Epidermal and dermal conditions

Synonym
contactallergy

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Trier, Afd Toxicologie
Source(s) of monetary or material Support: bedrijf,Wella, producent haarverf

Intervention

Keyword: hairdye, PPD, self-test

Outcome measures

Primary outcome

Outcome will be dichotomous: the presence or absence of a positive reaction at day 3 (72 hours) 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.

Secondary outcome

na

Study description

Background summary

More and more people are dying their hair, and a substantial number of young people are exposed to temporary tattoos. A principal component of hair dyes, and of some tattoo paints is p-Phenylenediamine (PPD). PPD is an allergen, and can occasionally cause very severe skin reactions, more severe that is usually seen from other contact allergens.
People who suspect that they may react to hair-dye want to know whether they are possibly allergic to it, before they dye their har or visit a hairdresser for haidying. A full dermatological examination with patch-testing is time-consuming, and puts constraints on the availability of dermatological services. A simple self-test with a patch on their forearm may give an indication about such a contact-allergy

Study objective

A pilot-study to the feasibility of a simple self-patchtest with a PPD containing hair-dye solution. The aim is to investigate whether a 30-minutes application of a patch-test gives a positive reaction in individuals who have a proven contact allergy to PPD.

Study design

Two patch-test chambers of 1x1 cm each will be applied to the volar forearm of 28 PPD allergic individuals for 30 minutes.
One patch-test will contain a mixture of hydrogen peroxide with a basic hair-dye cream; the mixture has a PPD concentration of 2%.
The control patch-test will contain the same mixture, but without PPD. The cream base consists of non-allergenic components that are used in many cosmetics.
After an application time of 30 minutes, the two patches will be removed, and the skin area washed with water.
Two days later (48 hours) the test-area will be read, and again three days later (72 hours). The anticipated reaction will be a redness, which will be graded according to the criteria of the ICDRG. The redness will disappear in a few days, similar to the reactions that may occur after a routine patch-test in a dermatology clinic.
Assuming a positivity rate of at least 80%, with a standard deviation of 7.5% (95% CI +/- 15%), the number of participants will be 28.

Study burden and risks

On the day of the patch-test application the time burden will be 35 to 40 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 5 minutes on day 2 and day three. There will be a travel time burden, but the participants will be offered to have these two readings done at their home or at a nearby location (e.g. a health center).
It is anticipated that the majority (80%) will develop a 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. The maximum permitted concentration of skin contact with PPD in hair-dye is 6%, which is much higher than the test concentration.

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

Positive patch-test on PPD or PTD

Exclusion criteria

-skinanomalies on the forearm
-severe skinanomalies elsewhere on the body
-immunosuppressive medication
-(wish to become) pregnant
-legally incompetent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-02-2008
Enrollment:	28
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	21-11-2007
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	NL19852.042.07