Consumer exposure to an oxidative hair dye.
A [14C]- labelled Toluene-2,5-diamine mass balance study

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The primary study objective is to establish the systemic exposure of consumers to a toluene-2,5-diamine containing hair dye formulation under actual use conditions during a typical hair dyeing procedure.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35782

Source
ToetsingOnline

Brief title
Consumer exposure to PTD-containing hairdye

Condition

- Other condition

Synonym
not applicable

Health condition

geen

Research involving

Human

Sponsors and support

Primary sponsor: The Procter & Gamble Company
Source(s) of monetary or material Support: Procter&Gamble

Intervention

Keyword: 5-diamine, absorption, hair dye, mass balance, Toluene-2

Outcome measures

Primary outcome

The primary study objective is to establish the systemic exposure of consumers

to a toluene-2,5-diamine containing hair dye formulation under actual use

conditions during a typical hair dyeing procedure.

Secondary outcome

Not applicable.

Study description

Background summary

At present, despite the widespread use of toluene-2,5-diamine in oxidative hair dyes, information on the extent of systemic absorption in humans after topical exposure to the scalp via hair dyeing is limited. The studies that are available have been either been conducted at a concentration of toluene-2,5-diamine that is lower than the maximum concentration permitted by the EU Cosmetics Directive or have not reported the concentration of toluene-2,5-diamine in the applied hair dye formulation. This study will determine the plasma AUC of toluene-2,5-diamine in humans after a hair dyeing procedure at the maximum concentration permitted by the Cosmetics Directive as well as at another lower concentration also used in dark shade hair dyes. The plasma AUC results in this study can be compared to the plasma AUC in rats after oral exposure at the dose showing no evidence of repeat dose toxicity (NOAEL). This comparison will allow a robust evaluation of the margin of safety for toluene-2,5-diamine based on systemic exposure.

Study objective

The primary study objective is to establish the systemic exposure of consumers to a toluene-2,5-diamine containing hair dye formulation under actual use conditions during a typical hair dyeing procedure.

Study design

The study is designed as a single topical application, open study.
The study will comprise
- 32 healthy volunteers (male/female)
- At least 4 professional hairdressers, with ample experience in hair dyeing.
- 3 study days per subject

The systemic exposure derived from an oxidative hair dyeing procedure will be evaluated after a single controlled application performed by a professional hairdresser of a [14C]-labelled hair dye formulation onto the hair of healthy subjects. Plasma, urinary and faecal levels of [14C]-toluene-2,5-diamine will give insight into the extent of systemic exposure. A mass balance will also be established in the study.
Two different hair colouring products containing different toluene-2,5-diamine concentrations will be evaluated, each on distinct groups of volunteers.

Intervention

Two days prior to the start of the study, volunteers will come to TNO for the sensibility test (allergy) for the hair dye. The study will last for 1 day (24h) and two mornings. On the first study day the hair will be dyed, washed and removed. Volunteers will stay at TNO during the night. The next morning the volunteers are allowed to go home (about 24 h after the onset of hair dying the previous day). The third morning they will come to TNO for the last time. At regular times blood samples will be taken (total 8x) and volunteers will collect urine and faeces for 48 h continuously.
Volunteers will come 4 times to TNO, including information, sensibility test and performance of the study.

Study burden and risks

The study substance is a common component of regular available hair dye. Animal studies show that this component is mainly metabolized after absorption. Therefore, no negative effects are expected after absorption of the study substance.
Nevertheless, since toluene-2,5-diamine is a known skin sensitizer, candidates will participate in an allergy alert test involving the finished test product 2 days prior to Day 01 of the study in order to check if hair dye exposure conditions would elicit any skin incompatibility reaction indicating possible

skin sensitization to toluene-2,5-diamine .
We do not anticipate any effects of the radiolable, because of of the relatively low dose.

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

1. Apparently healthy as assessed by the TNO Health and lifestyle questionnaire, limited Physical examination and results of the pre-study laboratory tests
2. Age [>= 18 and <= 45] years at Day 01 of the study
3. Having given their written informed consent
4: Willing to comply with the study procedures
5: Hair length of at least 5 cm at inclusion and willing to refrain from hair cutting and hair dye use until day 01 of the study

6: Willing to have their coloured hair completely clipped (bald headed!)
7: Willing to refrain from blood donation during the whole study
8: Willing to use adequate measures to avoid pregnancy during the whole study (females only)
9: Willing to accept use of all anonymous data, including publication, and the confidential use and storage of all data
10: Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned

Exclusion criteria

1. Participation in any clinical trial or medical treatment including administration of a radio labelled test substance up to 1 year before Day 01 of this study
2. Participation in any clinical trial including blood sampling and/or administration of substances up to 90 days before Day 01 of this study
3. Participation in any non-invasive clinical trial up to 30 days before Day 01 of this study, including no blood sampling and/or oral, intravenous, inhalatory administration of substances
4. Having a history of medical or surgical events that may significantly affect the study outcome, including metabolic or endocrine diseases, or dermatological diseases such as having dermatitis or particular skin diseases
5. A past history of having had a temporary henna tattoo applied or currently having a temporary henna tattoo
6. Prescribed medication (oral contraceptives and paracetamol excluded)
7. Bald headed or balding
8. Scars, cuts, wounds or dermal abnormalities on the scalp
9. Having a known allergy to hair colourants
10. Having a positive response to the allergy alert test to the test formulation (higher concentration), conducted 2 days in advance of Day 01 of the study
11. Positive pregnancy test (urine) (females)
12. Alcohol consumption more than 28 units/week (males) or 21 units /week (females) (1 unit of alcohol equals 10 grams of ethanol)
13. Recent blood donation (<1 month prior to the start of the study)
14. Not willing to give up blood donation during the study.
15. Pregnant or lactating or wishing to become pregnant in the period of the study
16. Personnel of TNO Quality of Life, their partner and their first and second degree relatives
17. Not having a general practitioner
18. Not willing to accept information-transfer concerning participation in the study, or information regarding his/her health, like laboratory results, findings at anamnesis or physical examination and eventual adverse events to and from his general practitioner.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2011
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	11-07-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL37285.028.11