Consumer exposure to an actual, dark-shaded oxidative hair dye. A [14C]-PPD labelled mass balance study*.

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Objective: The primary study objective is to establish the systemic exposure of consumers to PPD containing hair dye gel-based formulation under actual use conditions during a single typical hair dye procedure.

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

Summary

ID

NL-OMON32506

Source
ToetsingOnline

Brief title
Consumer exposure to PPD

Condition

- Other condition

Synonym
systemic exposure (absorption)

Health condition

nvt. diit is een veiligheidsonderzoek

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: L'Oreal R&D;Asnieres sur Seine;France

Intervention

Keyword: Clinical trial, Consumer exposure, PPD hair dye, Radiolabelled

Outcome measures

Primary outcome

Main study parameters/endpoints:

The individual concentration of [14C]-radioactivity (recoveries) in all non-biological samples will be established and expressed as percentages relative to the applied dose. For biological (blood and urinary) samples, the individual concentration versus time courses of [14C]-radioactivity will be established and expressed as percentages relative to the applied dose; results will also be expressed as [14C]-PPDeq or as [14C]-PPDeq per unit of mass (g) or volume (mL).

Secondary outcome

Establishing a Mass Balance

Study description

Background summary

Rationale: At present, despite the wide use of PPD, data on the extent of systemic exposure of consumers to this active ingredient in hair dyes under realistic use conditions is not available. Once knowledge on the extent of systemic exposure under typical *in-use* conditions has been gained, the risk for consumers using PPD-containing hair dye products can be assessed properly. This study is set up:
- to gain realistic data and to get insight on the systemic exposure to PPD in

consumers (n=16), resulting from a single hair dye procedure with a reduced PPD content (1% on head) performed by professional hairdressers under realistic conditions;
- to establish a *mass balance*, since [14C]-radiolabelled PPD is used in this study.

Study objective

Objective: The primary study objective is to establish the systemic exposure of consumers to PPD containing hair dye gel-based formulation under actual use conditions during a single typical hair dye procedure.

Study design

Study design: A single (topical) application, open study

Study approach: The systemic exposure derived from an oxidative hair dye procedure is evaluated following a single controlled application performed by professional hairdressers of a [14C]-labelled hair dye mixture onto the hair of healthy subjects. Plasma and urinary levels of [14C]-PPD will give insight into the extent of systemic exposure. A mass balance will also be established in the study.

Intervention

Intervention: A single typical hair dye procedure per subject will be performed by a professional hairdresser. Four professional hairdressers will be involved in the study.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The maximum amount of [14C]-radioactivity handled or to come in contact with will not exceed 3.6MBq per subject in this study. This level of radioactivity is chosen to gain reliable data on the systemic exposure of consumers to hair dyeing. Based on recent human data, the physical-chemical properties of the active ingredient (not volatile), the skin protection by gloves, the combined reaction with the coupler (irreversible binding to the hair shaft), it is expected that the dermal and inhalation exposure for the professional hairdresser will be low to negligible. The latter was confirmed by the recently conducted and reported hairdresser exposure study [2].
Possible skin contact with hair dye results in a radiation dose for the skin and for the total body which is dependent on the fraction of radioactive material to come in contact with skin, the fraction absorbed by the skin and

the penetration via the skin into the human body. Recently reported human data in literature [1] show that the dermal penetration of PPD, directly in contact for 30 minutes with bare skin, amounted on average to about 0.5% with a maximum of 1.02%, expressed as percentage of the applied dose. Since in this study the PPD content of the used hair dye formulation is reduced (1% instead of 2% on head) the possible absorption is expected to be lower.
The Nuclear Research and Consultancy Group (NRG) has performed calculations on the skin dose, the internal dose and the effective dose for an exposure duration to the hair dye comparable to the daily life situation in hair dyeing [3]. The effective radiation dose (body burden) per subject is estimated to be maximally 0.025 mSv.

In conclusion, the radiation dose received by the subjects in this study will be well below the Euratom dose limit (body burden; 0.025mSv) of 1mSv/year and therefore their risk will only be slightly increased due to their participation in this study.
Based on the fact that [14C] is a radiation emitter with low energy it is concluded that risk for the professional hairdressers and workers in the Clinical Research Unit is not enhanced.

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:Female/Male; Age 18-45 years;
2:Healthy as assessed by health questionnaire, physical examination, clinical chemistry a pregnancy test in urine will be done.
3:Prescribed medication (oral contraceptives and paracetamol excluded)
4:Having given their written informed consent
5:Willing to have their coloured hair completely clipped (bald headed!)
6:Willing to refrain from blood donation during the whole study
7:Willing to use adequate measures to avoid pregnancy during the whole study (females only)
8:Willing to accept use of all anonymous data, including publication, and the confidential use and storage of all data
9: Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned
10: Willing to refrain from hair cutting to let grow their hair to about a 5 cm length on day 01 of the study

Exclusion criteria

1:Participation in any clinical trial including blood sampling and/or administration of substances up to 90 days before Day 01 of this study
2:Participation in any clinical trial or medical treatment including administration of a radiolabelled test substance up to 1 year before Day 01 of this study
3: Positive pregnancy test (urine) (females) or lactating
4: Prescribed medication (except oral contraceptives and paracetamol)
5: Alcohol consumption more than 28 units/week (males) or 21 units/week (females); 1 unit of alcohol equals 10 grams of ethanol
6:Having a known allergy to PPD
7: Having a positive response to the retro-auricular sensitisation test to PPD, conducted 2 days in advance of Day 01 of the study

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):	01-09-2008
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO

Date:	14-08-2008
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	NL24586.028.08