Blootstelling van consumenten aan donkergekleurde haarverf. Een 14C-gemerkte massa balanstudie.

Gepubliceerd: 14-08-2008 Laatst bijgewerkt: 06-05-2024

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.

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Overige aandoening
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON32506

Bron
ToetsingOnline

Verkorte titel
PPD absorptie uit haarverf

Aandoening

- Overige aandoening

Synoniemen aandoening
systemische blootstelling (interne belasting)

Aandoening

nvt. diit is een veiligheidsonderzoek

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: TNO
Overige ondersteuning: L'Oreal R&D;Asnieres sur Seine;France

Onderzoeksproduct en/of interventie

Trefwoord: Blootstelling van consumenten, Klinische studie, PPD haarverf, Radioactief gemerkt

Uitkomstmaten

Primaire uitkomstmaten

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).

Secundaire uitkomstmaten

Establishing a Mass Balance

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Inschatting van belasting en risico

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.

Contactpersonen

Publiek

TNO

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Wetenschappelijk

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Locaties

Landen waar het onderzoek wordt uitgevoerd

Netherlands

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Vrouw/man; 18-45 jaar
Gezond op basis van vragenlijstonderzoek (anamnese), lichamelijk onderzoek, klinische chemie
Negatieve zwangerschaptest
Getekend inform consent
Bereid te zijn al het haar te laten afscheren
Bereid te zijn anti-conceptie te gebruiken
Bereid te zijn het haar (vooraf) te laten groeien tot ±5cm (op dag 1 van de studie)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Deelname aan klinisch onderzoek met radioactieve stoffen korter dan 1 jaar geleden
Positieve zwangerschaptest
Gebruik van voorgeschreven medicijnen (de'pil'en af en toe paracetamol uitgesloten)
Allergisch zijn voor PPD
Een positieve uitslag van de PPD sensibilisatie test

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Blindering:	Open / niet geblindeerd
Controle:	Geen controle groep
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2008
Aantal proefpersonen:	16
Type:	Werkelijke startdatum

Ethische beoordeling

Goedgekeurd WMO Datum:	14-08-2008
Soort:	Eerste indiening
Toetsingscommissie:	METC Brabant (Tilburg)

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
CCMO	NL24586.028.08