

Consumenten blootstelling aan oxidatieve haarverfen. Een [14C]-PPD gemerkte massabalansstudie.

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Zie engelse versieThe primary study objective is to establish the systemic exposure of consumers to PPD during a single typical hair dye procedure.

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

Samenvatting

ID

NL-OMON30980

Bron

ToetsingOnline

Verkorte titel

PPD opname uit haarverf

Aandoening

- Overige aandoening

Synoniemen aandoening

systemische belasting (interne belasting)

Aandoening

nvt. dit is een veiligheidsonderzoek

Betreft onderzoek met

Mensen

Ondersteuning

Primaire sponsor: L'Oreal R&D, Worldwide Safety Evaluation

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

Onderzoeksproduct en/of interventie

Trefwoord: Consument blootstelling, Klinische studie, PPD haarverf, Radioactief gemerkt

Uitkomstmaten

Primaire uitkomstmaten

Zie engelse versie

The individual concentration versus time courses 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, results will also be expressed as [14C]-PPDeq or as [14C]-PPDeq per

unit of mass (g) or volume (mL).

Secundaire uitkomstmaten

Zie engelse versie

Establishing a Mass balance

Toelichting onderzoek

Achtergrond van het onderzoek

Zie engelse versie

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 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

Zie engelse versie

The primary study objective is to establish the systemic exposure of consumers to PPD during a single typical hair dye procedure.

Onderzoeksopzet

Zie engelse versie

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 onto the hairy scalp 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

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

Inschatting van belasting en risico

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.

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

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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)

1. Vrouw/man; 18-45 jaar
2. gezon op basis vragenlijstonderzoek (anamnese), lichamelijk onderzoek, klinische chemie
3. Zwangerschaptest (negatief)
4. Getekend informed consent
5. Bereid te zijn al het haar te laten afscheren
6. Bereid te zijn anti-conceptie te gebruiken
7. Bereid te zijn het haar (vooraf) te laten groeien to 5 cm lengte en niet te knippen

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. deelname aan een klinisch onderzoek met radioactieve stoffen korte dan 1 jaar
2. Positieve zwangerschapstest
3. Gebruik van voorgeschreven medicijnen (de 'pil' en af en toe paracetamol uitgesloten)
4. Allergisch zijn voor PPD
5. 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: 12-06-2007

Aantal proefpersonen: 16

Type: Werkelijke startdatum

Ethische beoordeling

Goedgekeurd WMO

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

NL16849.028.07