

Safety of a PPD-Hair dye derivative in PPD-allergic subjects

Submission date 29/03/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 31/03/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/11/2021	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Paraphenylenediamine (PPD) is a chemical that is a common ingredient in permanent hair dye. Allergies to PPD are relatively common and use of products containing PPD can trigger an allergic reaction called contact dermatitis, in which the skin becomes inflamed (swollen), where the product has touched it. 2-Methoxymethyl-p-phenylenediamine (ME-PPD) is a PPD derivative which has recently been developed. Studies have shown that ME-PPD may be less allergenic (likely to cause an allergic reaction), and so products containing ME-PPD rather than PPD could be a good alternative to those with PDD allergies. The aim of this study is to compare the allergenic effects of PPD and ME-PPD on people who are allergic to PPD.

Who can participate?

Adults with a PPD allergy

What does the study involve?

All participants attend a total of three clinic visits over the course of one week. On the first visit, participants have an allergy test in which three different chemicals (PPD, ME-PPD and a control substance that does not contain any dye chemicals) are applied to the skin on the right arm. After thirty minutes, the chemicals are washed off and examined to see if there has been a skin reaction. These sites are also examined on the second and third visit (48 and 72 hours). At the first study visit, a sticky disc coated with ME-PPD is also placed on the participants back and left in place for 48 hours (the second study visit), at which time it is removed and the skin examined for signs of an allergic reaction.

What are the possible benefits and risks of participating?

There are no direct benefits to participants taking part in this study. There is a risk that participants will experience skin irritation, discomfort and itchiness during and after the patch test.

Where is the study run from?

University of Maryland, Baltimore (USA)

When is the study starting and how long is it expected to run for?
December 2014 to December 2015

Who is funding the study?
Procter and Gamble GmbH (Germany)

Who is the main contact?
Dr Anthony Gaspari
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Tolerability of 2-methoxymethyl-p-phenylenediamine in p-phenylenediamine Allergic Volunteers using Allergy Alert Test: A Pilot Study

Acronym
Me-PPD Study

Study objectives
Methoxymethyl p-phenylene diamine (PPD) is a safe, well-tolerated hair dye in PPD allergic subjects.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of the University of Maryland Baltimore, 03/12/2014, ref: HP-00060991

Study design

Observational cohort study

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Allergic contact dermatitis

Interventions

The vehicle (Koleston Perfect formula without fragrance) containing the hair dye precursor (4% ME-PPD, free base) and couplers (1.9% 2-methylresorcinol and 1.9% 2-methyl-5-hydroxyethylaminophenol), as well as the hydrogen peroxide solution (6% (w/w) Welloxon) will be provided by P&G. The hair dye test product will be always freshly prepared by mixing the tint (containing ME-PPD and the couplers) with the hydrogen peroxide solution using a small wooden stick (1:1, 90 microliters each). An amount of 100 microliters of the finished ME-PPD containing product is applied to the filter paper of the van der Bend Chambers® (Brielle, the Netherlands, 1 cm²) using a pipette (infinite dose, 100 mg/cm²). A dye-free test product was used as control. The filled chambers were removed from the tape and directly placed on the skin of the lower arms. The chambers were additionally re-secured in the same position with 2 small stripes of tape (3M) across the plastic connections attached to the chamber (occlusion). After 30 minutes the formulations were gently rinsed off with a commercial shampoo and water to simulate hair dyeing use conditions. Responses were recorded at day 2 (D2, first reading after 48h) and day 3 (D3, second reading after 72h) and graded according to the ICDRG criteria.

Intervention Type

Device

Primary outcome(s)

Skin test reactivity is determined by Anthony Gaspari and Amir Zahir at baseline, 30 minutes, 48 and 72 hours using a standard contact dermatitis scoring system (ICDRG criteria).

Key secondary outcome(s)

No secondary outcome measures.

Completion date

02/12/2015

Eligibility

Key inclusion criteria

1. Aged 18 years and over
2. History of hair dye intolerance
3. Positive patch test to PPD

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

20

Key exclusion criteria

1. Life threatening diseases
2. Poor health
3. Anaphylaxis to PPD

Date of first enrolment

05/01/2015

Date of final enrolment

02/11/2015

Locations**Countries of recruitment**

United States of America

Study participating centre**University of Maryland**

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United States of America

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Sponsor information

Organisation

Procter and Gamble GmbH

ROR

<https://ror.org/02t2pyr24>

Funder(s)

Funder type

Industry

Funder Name

Procter and Gamble GmbH

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2016	18/11/2021	Yes	No