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

Submission date
29/03/2016

Recruitment status
No longer recruiting

Registration date
31/03/2016

Overall study status
Completed

Last Edited
18/11/2021

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

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 measure
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).

Secondary outcome measures
No secondary outcome measures.

Overall study start date
03/12/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

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
Department of Dermatology
419 W. Redwood St., Ste. 260
Baltimore
United States of America
21201

Sponsor information

Organisation
Procter and Gamble GmbH

Sponsor details
Sulzbacher StraBe 40
Schwalbach am Taunas
Germany
65824

Sponsor type
Industry

ROR
https://ror.org/02t2pyr24

Funder(s)

Funder type
Industry

Funder Name
Procter and Gamble GmbH

Results and Publications

Publication and dissemination plan
Planned publication in JAMA Dermatology.

Intention to publish date
01/09/2016

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