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A study to develop a method to analyse the uptake and degradation of a spice and flavouring agent known as eugenol

Submission date
02/09/2013

Recruitment status
No longer recruiting

Registration date
10/01/2014

Overall study status
Completed

Last Edited
06/12/2019

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Eugenol is a natural chemical substance which is used as a spice and flavouring in a wide variety of consumer products including in so-called kretek (clove) cigarettes to which this spice is added. So far, very little is known about how the human body takes up and gets rid of eugenol. To clarify this point, we want to develop and validate a method for detecting eugenol and its degradation products in human urine.

Who can participate?
Non-smokers who do not have any health problems can participate in this study.

What does the study involve?
During the study, participants will be asked to collect their urine samples over a period of 24 hours after having a eugenol-free diet. Similarly a further 24 hours urine sample will be collected after the same participants have had eugenol-rich food. For assessing your health a small amount of blood (about 15 mL) will be taken at the initial examination. Additional blood samples during the study are not expected but may be taken for medical reasons.

What are the possible benefits and risks of participating?
In general, no side effects are expected; the substance to be examined (eugenol) is supplied with normal food in the form of natural additives such as spices and flavours. Occasionally, however, gastrointestinal (digestive system) symptoms can occur if your body is not used to these spices, flavours or additives. The skin puncture for blood sampling may give rise to a bruise, local irritation or swelling. In very rare cases it can lead to infection, damage to nerve injury or swelling of the veins in the area of the injection site. Allergic reactions could occur after having eugenol in the diet. For this reason you can only participate in this study if you are not allergic to any foods or spices or have not had an allergic reaction in the past. Allergic reactions can occur in the form of redness, swelling, itching, fever, flushing, vomiting, breathing difficulties or massive circulatory failure. Participation in the study provides no health benefits or any other benefit for the participating subjects.

Where is the study run from?
The study is run from British American Tobacco (Investments) Ltd, UK.

When is study starting and how long is it expected to run for?
The study started in August 2013 and lasted for one month.

Who is funding the study?
British American Tobacco (Investments) Ltd, UK.

Who is the main contact?
Dr Chris Proctor
christopher_proctor@bat.com

Contact information

Type(s)
Scientific

Contact name
Dr Chris Proctor

Contact details
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British American Tobacco (Investments) Ltd.
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-
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Additional identifiers

Protocol serial number
BAT3113004

Study information

Scientific Title
A single-centre, open-label study for the collection of urine samples as part of a method development and validation process for eugenol biomarkers in healthy male volunteers

Study objectives
The analytical methodology has the ability to detect eugenol metabolite in urine.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Committee of Arztekramer Hamburg, Germany, 08/07/2013, ref: PV4511

Primary study design
Interventional

Study design
Single-centre open-label one-way study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
This study involves healthy adult never smokers to obtain information on biomarkers of exposure to eugenol in urine

Interventions
The clinical study will be conducted in compliance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practice (GCP). Participants will be required to read the Subject Information prior to providing their written consent by signing the informed consent form.

Collection of urine samples for the development of eugenol biomarker in urine.

Day 1: 08:00 am to next day, subjects consume a eugenol-free diet
Day 2: 08.00 am to 20:00 pm, subjects collect a urine sample, after 20.00 pm you will be given a eugenol-rich diet
Day 3: subjects collect urine samples for 12 hours

Safety assessments include documenting any reported adverse events. Any concomitant medications for the adverse event will also be documented on all study days, as well as a physical examination, the assessment of vital signs (blood pressure, pulse rate, body temperature), a 12-lead ECG, standard clinical laboratory assessments (urinalysis, hematology, clinical chemistry) and serology tests (HIV, hepatitis B and C) at screening.
A urine drug screen, a urine cotinine test and an alcohol breath test will be done at screening and at Day 1.The safety of the study participants will be monitored throughout the study.

Principal Investigator:
Werner Weber
Senior Medical Advisor
Momentum Pharma Services GmbH

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
To quantify via GC-MS/MS method 'total' eugenol biomarker in 24 hours urine after treatment with glucuronidase/sulfatases

Key secondary outcome(s)
N/A

Completion date
10/09/2013

Eligibility

Key inclusion criteria
1. Aged between ≥ 18 and ≤ 50 years
2. Body Mass Index (BMI) ≥ 18 and ≤ 30 kg/m² inclusive
3. Provide written informed consent
4. Subjects must be able to communicate well with the Investigator, to understand and comply with the requirements of the study, and be judged suitable for the study in the opinion of the Investigator
5. Non-smokers
6. Healthy male volunteers, as judged by a medical history, concomitant medication, physical examination, vital signs, 12-lead ECG and laboratory safety tests
7. HIV and Hepatitis B and C tests, taken within 21 days prior to the start of the study, must be negative
8. Willingness to avoid eugenol-containing foods (e.g., cola, curry, clove, cinnamon, nutmeg, basil, dill, star anise) and dental surgery products such as mouthwash 48 h prior to study start
9. Willingness to comply with specific diet restrictions during study course: eugenol-free diet (no cola, curry, clove, cinnamon, nutmeg, basil, dill, star anise) and eugenol-rich diet (cinnamon, curry, clove, bay leaves, turmeric, pumpkin bread, cola-type drinks and coffee)
10. No allergy against eugenol or against eugenol-containing food/spices like cola, curry, clove, cinnamon, nutmeg, basil, dill and star anise
11. Subject understands the study procedures and signs forms providing informed consent to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Male

Key exclusion criteria
1. History or presence of significant cardiovascular disease
2. Known allergy against any food
3. Existing gastrointestinal disorder
4. History of alcohol or drug abuse or a positive breath or urine test, respectively at screening

and on Day 1
5. Subjects should not drink methylxanthine- and caffeine-containing drinks (e.g., cola, coffee) during the wash-out and eugenol-free diet phase
6. Clinically significant illness within 14 days prior to start of study
7. Participation in a clinical trial with an investigational drug within 8 weeks prior to the first dosing
8. Use of any prescription drug within 2 weeks before Day 1 and use of any OTC drug within 3 days before Day 1
9. Diet, which in the opinion of the Investigator, deviates from a normal diet (e.g., vegetarians may be acceptable, vegans are not acceptable)
10. Subjects who have urinary cotinine levels similar to that of smokers (≥30 ng/mL, levels ≥ 2 according to the NicAlert™ Scale)

Date of first enrolment
10/08/2013

Date of final enrolment
10/09/2013

Locations

Countries of recruitment
United Kingdom

Germany

Study participating centre
Chief Scientific Officer
Southampton
United Kingdom
SO15 8TL, UK

Sponsor information

Organisation
British American Tobacco (Investments) Ltd. (UK)

ROR
https://ror.org/01znsh139

Funder(s)

Funder type
Industry

Funder Name
British American Tobacco (Investments) Ltd. (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration