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# Malodour study to judge bad breath in subjects who smoke cigarettes compared to e-cigarette smokers and non-smokers

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 05/11/2018 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 20/11/2018 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 26/04/2021 | Oral Health | [_] Record updated in last year |

## Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether vaping keeps the oral cavity (mouth) cleaner and healthier than conventional cigarettes and similar to that of non-smokers.

Who can participate?
Smokers, e-cigarette users and non-smokers aged 21-60

What does the study involve?
Participants are assessed by a dentist and have a breath sample taken. They are then asked to smoke their own cigarette or e-cigarette (or nothing for non-smokers) and provide breath samples again.

What are the possible benefits and risks of participating?
Participants can choose between being a non-smoker, e-cigarette user or conventional cigarette smoker depending on their results, and could benefit from healthier gums and soft palate tissue. There are no risks involved as participants will be using their own products and the sample measurements are non-invasive.

Where is the study run from?
Alba Science Ltd (UK)

When is the study starting and how long is it expected to run for?
August 2018 to December 2018

Who is funding the study?
British American Tobacco (UK)

Who is the main contact?
Mr George Hardie

# Contact information

### Type(s)
Scientific

### Contact name
Mr George Hardie

### Contact details
R&D Centre, Regents Park Road
Southampton
United Kingdom
SO15 8TL

# Additional identifiers

### Protocol serial number
213418/GRD-PLN-1356

# Study information

### Scientific Title
Pilot study to determine the oral health and levels of volatile sulphur compounds (VSCs) in the breath of human volunteers before and after cigarette and e-cigarette product use, using SIFT-MS and OralChroma

### Study objectives
To check if conventional cigarette smokers breath is more volatile compared to either e-cigarette users or non-smokers.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Reading Independent Ethics Committee, 17/10/2018, ref: RIEC091018-6

### Study design
Single-centre oral evaluation study

### Primary study design
Observational

### Study type(s)
Diagnostic

### Health condition(s) or problem(s) studied
Oral health looking at effects on breath

### Interventions

Collection of breath for analysis on SIFT-MS and OralChroma to detect for Volatile Sulphur Compounds and also to collect gingival crevicular fluid which will be identified and quantified for protein levels.

Volunteers will be enrolled onto the clinical study after completing a form (informed consent) that they can understand, they will then be assessed for their oral health and be put forward to the in-life phase of the clinical study. Volunteers will be asked to have a baseline assessment completed by a dentist, then moved to another area of the clinical site to have a baseline breath sample taken. This sample will be analysed on a machine built to check on the identified criteria set out in the protocol. Volunteers will then be asked to smoke their own product cigarette, e-cigarette or nothing for non-smokers then are asked back to undertake breath samples similar to their baseline sample. Once complete volunteers will be released from the study and paid for their time as agreed when signing the informed consent form.

### Intervention Type
Other

### Primary outcome(s)
Measured from breath samples collected at baseline and after product use (or air in non-smokers):
1. Volatile Sulphur Compound levels, measured using SIFT-MS
2. Volatile Sulphur Compound levels, measured using OralChroma

### Key secondary outcome(s))
1. Extrinsic tooth staining of 12 anterior teeth, measured using the Lobene Tooth Stain Index at screening/baseline
2. Protein analysis of gingival crevicular fluid (conducted by Sponsor), cytokines levels measured using Meso Scale Discovery multiplex assay kits in Timepoint 0 (T0) samples

### Completion date
21/12/2018

## Eligibility

### Key inclusion criteria
1. Males or non-pregnant, non-lactating females, aged 21-60 years inclusive. Age verification will be performed by checking government issued identification (e.g. passport or driving licence) during screening
2. Good general health as judged by the Investigator or their appropriately qualified designee based on medical history
3. Subjects will have given their written informed consent to participate in the study and will have agreed to abide by the study restrictions. Subjects must demonstrate the ability to comprehend the Informed Consent Form (ICF), be able to communicate well with the Investigator or their appropriately qualified designee, understand and comply with the requirements of the study, and be judged suitable for the study in the opinion of the Investigator or their appropriately qualified designee
4. Subjects will be willing to refrain from consuming alcohol within 48 hours prior to Screening and study visit
5. Subjects will be willing to refrain from consuming coffee, onions, garlic and spicy food, for 48 hours prior to test visit
6. Good oral health with no diseases or conditions which could affect the study/have an adverse

impact on the volunteer including severe gingivitis, grossly carious lesions and periodontal disease
7. At least 12 natural teeth, with at least 1 tooth suitable for GCF sampling (in the opinion of the dentist) per quadrant
8. No scale and polish for 6 months prior to screening for all groups
9. SMOKERS:
9.1. Subjects will be regular smokers of commercially manufactured filter cigarettes and including menthol cigarettes
9.2. Subjects will have smoked for at least 3 consecutive years prior to Screening
9.3. Subjects will typically smoke at least 10 cigarettes per day and an exhaled breath CO level ≥ 7 ppm at Screening measured using a CO meter
10. E-CIGARETTE USERS:
10.1. E-cigarette user of a minimum of 200 puffs per day or more for more than 6 months
10.2. Subjects are to be exclusive e-cigarette users for a minimum of 6 months, history of tobacco smoking and transition to e-cigarette to be documented
11. NON-SMOKERS:
11.1. Subjects will have never smoked (<100 cigarettes in their life and none within 1 year prior to Screening) and will continue to not smoke or use any form of tobacco or nicotine containing products for the duration of the study
11.2. Subjects with an exhaled breath CO level < 2 ppm at Screening

## Participant type(s)
Healthy volunteer

## Healthy volunteers allowed
No

## Age group
Adult

## Sex
All

## Total final enrolment
33

## Key exclusion criteria
1. Signs of gross or untreated caries or of significant periodontal disease, which, in the opinion of the study dentist, either would affect the scientific validity of the study or, if the subject were to participate in the study, would affect their wellbeing
2. Orthodontic or prosthetic appliances (fixed or removable), including dental implants
3. Tongue or lip piercing
4. Currently participating in other dental trials
5. Pregnant or breastfeeding women
6. Medical condition and/or regular use of any medication which might affect the outcome of the study including:
evidence or recent (within 4 weeks) history of bronchitis, tonsillitisor sinusitis, current respiratory infection, oesophageal reflux, colds, flu, sore throat, severe xerostomia, either self-reported or evidenced through oral examination, diabetics, current use or use of any antibiotics within 14 days prior to screening
7. Medications or supplements which may impact oral mouth odour within 7 days prior to the

test visit, specifically zinc-containing products
8. Current use or use of anti-inflammatory medication within 4 weeks of screening
9. Subjects who have a significant history of alcoholism or drug/chemical abuse within 24 months prior to Screening, as determined by the Investigator
10. Subjects who use “roll your own” or tobacco heating products
11. Subjects who use chewing tobacco or snuff
12. Subjects unable to attend for all visits
13. Employees and immediate relatives of the tobacco industry and the clinical site

### Date of first enrolment
31/10/2018

### Date of final enrolment
30/11/2018

## Locations

### Countries of recruitment
United Kingdom

Scotland

### Study participating centre
**Alba Science Ltd**
24 Broughton Street
Edinburgh
United Kingdom
EH1 3RH

## Sponsor information

### Organisation
British American Tobacco

### ROR
https://ror.org/01znsh139

## Funder(s)

### Funder type
Industry

**Funder Name**
British American Tobacco

**Alternative Name(s)**

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

**IPD sharing plan summary**
Other

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | | 12/11/2019 | 26/04/2021 | No | No |