

# A five year non-residential multi-centre observational study conducted to track any changes in mouth level exposure and salivary and urinary biomarkers from healthy smokers smoking in their normal environment

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		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 05/05/2009	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 16/06/2015	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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Scientific

### Contact name

Dr Stephan de la Motte

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**Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

**Study information****Scientific Title**

Longitudinal study on long-term smoking habits using biomarker-supported determination of exposure to smoke

**Study objectives**

If subjects switch between factory made cigarettes with different International Organization for Standardization (ISO) tar yields, there should be a measurable difference in the levels of mouth level exposure, urinary / salivary biomarkers, and daily cigarette consumption.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics Committee of Bayerischen Landesärztekammer, 04/07/2008, ref: 08036

**Study design**

Longitudinal non-residential multi-centre observational study

**Primary study design**

Observational

**Secondary study design**

Longitudinal study

**Study setting(s)**

Other

**Study type(s)**

Other

**Participant information sheet**

Not available in web format, please use the contact details below to request a Subject Information Sheet

**Health condition(s) or problem(s) studied**

Smoking behaviour

**Interventions**

08/03/2013: Please note that this study was stopped in December 2012.

The five year longitudinal study is ongoing at ten sites. Approximately 1,000 smokers (100 per site) will be enrolled. All subjects will be screened to rule out medical problems. Healthy smokers may get enrolled in the study on the day of screening or as per their convenience.

Study subjects are instructed to perform the following activities during 12 days every 6 months:  
Day 1 (Visit 1): Visit Investigator site for informed consent and undergo screening  
Days 2-8: Collection of all their smoked cigarettes in their routine day-to-day environment  
Day 9 (Visit 2): Visit test location to receive study supply including cigarettes, filter cutter, 2 L polyethylene bottles for urine collection. Smokers will be instructed about filter collection and 24 hour urine collection procedures. Smokers will continue collection of their smoked cigarettes. Accountability of smoked cigarettes collected from Days 2-8.  
Day 10: Continue collection of smoked cigarettes. Receive telephonic instructions for activities to be performed on Day 11  
Day 11: Smokers begin the collection of part filters from all cigarettes smoked as provided on Day 9. Smokers also begin collection of urine passed from the morning excluding the first void, into the urine bottles provided.  
Day 12 (Visit 3): Completion of 24 hour urine collection including the first void of Day 12. Part filter collection is also completed which would be the last cigarette smoked prior to taking the first void of Day 12. Smokers will visit the Investigator site between 3.00-9.00 pm, for collection of spot saliva sample and questionnaire administration. Collection of part filters and urine from Day 11 and 12 and unsmoked cigarettes are returned. Accountability of smoked cigarettes collected from Days 9-10.

Telephone interview will be conducted to check the inclusion and exclusion criteria of all participants prior to study assessments.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

To track the following every six months over a five year period:

1. Spontaneous switching from 10 mg ISO tar cigarette to other cigarettes with different ISO tar yields, assessed by telephone interviews
2. Mouth level exposure, assessed by part filter analysis
3. Smoking behaviour

4. Levels of biomarkers in urine (nicotine, cotinine, trans-3'-hydroxycotinine, nicotine-N-glucuronide, cotinine-N-glucuronide, trans-3'-hydroxycotinine-O-glucuronide) and saliva (cotinine and trans-3'-hydroxycotinine)

### **Secondary outcome measures**

To track the following every six months over a five year period:

1. Compensatory smoking behaviour, assessed by published formula
2. Levels of additional biomarkers/metabolites in urine when validated methods are available in future

### **Overall study start date**

09/03/2009

### **Completion date**

09/03/2014

### **Reason abandoned (if study stopped)**

Objectives no longer viable

## **Eligibility**

### **Key inclusion criteria**

1. Healthy males and females aged between 21 and 64 years of age who currently smoke the same 10 mg ISO tar cigarettes. If female, subjects will be non-pregnant and non-lactating.
2. Smokers who have been smoking 10 mg ISO tar product for more than 6 months and regularly smoke  $\geq 8$  cigarettes per day
3. Subjects will have given their written informed consent to participate in the study

Note: Study participants will independently purchase their cigarettes for personal use. The sponsor will only provide cigarettes for Days 9-11 as stated in the Interventions field.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

1,000 smokers

### **Key exclusion criteria**

1. Subjects with an existing chronic disease
2. Participated in a different investigation on smoking behaviour within the last 6 months
3. Subjects who are currently trying to quit smoking
4. Subjects who as part of their jobs are involved in public relations or advertising for the tobacco industry, the sales or manufacture of tobacco goods, or their immediate family

**Date of first enrolment**

09/03/2009

**Date of final enrolment**

09/03/2014

## **Locations**

**Countries of recruitment**

England

Germany

United Kingdom

**Study participating centre**

**British American Tobacco (Investments) Ltd**

Southampton

United Kingdom

SO15 8TL

## **Sponsor information**

**Organisation**

British American Tobacco (Investments) Ltd (UK)

**Sponsor details**

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**Sponsor type**

Industry

**Website**

<http://www.bat-science.com>

**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

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	12/04/2014		Yes	No