

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

Submission date 22/04/2009	Recruitment status Stopped	☐ Prospectively registered
		☒ Protocol
Registration date 05/05/2009	Overall study status Stopped	☐ Statistical analysis plan
		☐ Results
Last Edited 16/06/2015	Condition category Mental and Behavioural Disorders	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers**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

Primary study design

Observational

Study design

Longitudinal non-residential multi-centre observational study

Study type(s)

Other

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(s)

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)

Key secondary outcome(s)

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

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 ≥ 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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Germany

Study participating centre

British American Tobacco (Investments) Ltd

Southampton

United Kingdom

SO15 8TL

Sponsor information

Organisation

British American Tobacco (Investments) Ltd (UK)

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

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/04/2014		Yes	No