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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

Registration date
05/05/2009

Overall study status
Stopped

Last Edited
16/06/2015

Condition category
Mental and Behavioural Disorders

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

Protocol serial number
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 Landesaerztekammer, 04/07/2008, ref: 08036

Study design
Longitudinal non-residential multi-centre observational study

Primary study design
Observational

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes