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A research study to investigate the absorption of nicotine from a number of Tobacco Products and an Over the Counter (OTC) Nicotine Gum

Submission date 29/01/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/01/2010	**Overall study status** Completed	
Last Edited 11/01/2013	**Condition category** Other	

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
8201-712

Study information

Scientific Title
A Randomised, Pharmacokinetic Study of Multiple Tobacco Products and an Over the Counter (OTC) Nicotine Product in Healthy Subjects

Study objectives
The pharmacokinetic study will determine the plasma concentrations of nicotine at pre-determined time points, following single dose administration of different snus products, a cigarette and an OTC oral nicotine gum.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Central Ethical Review Board, Stockholm, Sweden approved on the 11th of November 2009 (ref: dnr Ö 20-2009)

Study design
Single dose open label randomised crossover controlled study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Pharmacokinetic study with healthy volunteers

Interventions
The study will include five various tobacco related products (snus products, a cigarette) and an OTC oral nicotine gum. All subjects in the study would be daily snus users and occasional smokers.

Subjects will attend the study site for a pre-study screening visit within 30 days of entry into the study. Subjects who satisfy the inclusion/exclusion criteria will attend the study site six times to receive the test products. At each visit subjects will receive one of the products, assigned at random. Subjects will remain in the clinic for a period of 4 hours.

The following procedures will be performed during the study visits:
1. Blood sample collection to determine the CYP2A6 genotype (only at Visit 1) and nicotine concentrations in plasma.
2. Sensory questionnaire for evaluation of oral tobacco products.
Subjects will continue to attend clinic a minimum of every two days for product administration visits until they have received all products in the study. The Investigator will follow up all study Subjects to obtain information on any new adverse events and new/changes to concomitant medication within seven days of the last treatment visit. The study ensures all measures to comply with International Conference on Harmonisation-Good Clinical Practice (ICH-GCP) guidelines.

All Subjects will be provided Health advice and information on tobacco cessation help-lines

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Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Nicotine in plasma

Key secondary outcome(s))
Sensory evaluation of oral tobacco products

Completion date
01/08/2010

Eligibility

Key inclusion criteria
1. Subjects will be males or non-pregnant, non-lactating females between 19 and 55 years of age inclusive. Female subjects must be postmenopausal (absence of menstrual discharge for at least two years and a serum FSH exceeding 30IU/L) or premenopausal/ perimenopausal with effective contraception (oral, injected or implanted contraceptives, intrauterine device or status after operative sterilisation).
2. Subjects must be in good health as determined by
2.1. medical history
2.2. 12-lead Electrocardiogram (ECG)
2.3. vital signs
2.4. physical examination
3. Subjects must have a body mass index (BMI) between 18 and 30 kg/m2 inclusive. Male subjects must have a weight between 50 and 110kg and female subjects between 40 and 90kg.
4. Subjects will have results of clinical laboratory evaluations within normal ranges (or if outside the normal ranges deemed as not clinically significant by the Investigator).
5. Subjects will have negative results for the drug screening test.
6. Subjects will have given their written informed consent to participate in the study and to abide by the study restrictions.
7. Subjects will be occasional smokers of 9-10mg ISO Tar cigarettes (on average, no more than 40 cigarettes per week) and daily snus users, who use snus products under their upper lip. If the subjects are pouched users they must use products of pouch weights 0.8g and above. They must have used snus and cigarettes for a minimum of six months prior to the start of the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Subjects who have a history of, or clinically active significant, medical disorders incluing:
1.1. neurological
1.2. gastrointestinal
1.3. renal
1.4. hepatic
1.5. cardiovascular
1.6. psychiatric
1.7. respiratory
1.8. metabolic
1.9. endocrine
1.10. haematological disease
1.11. other major disorders
2. Subjects who have taken prescription or non-prescription drugs in the 14 days prior to the Screening Visit excluding oral contraceptives.
3. Subjects who have used any medication which interferes with the cyclo oxygenase pathway (anti-inflammatory drugs such as aspirin or ibuprofen) in the 14 days prior to the start of the study (Screening visit).
4. Subjects who have received any medications known to chronically alter nicotine absorption or elimination processes within 30 days of the first product administration.
5. Female subjects, who are pregnant or become pregnant during the course of the study.
6. Subjects who have lost or donated (more than 450ml) blood, plasma or platelets within the 3 months preceding the first product administration.
7. Subjects who are participating in another clinical research study.
8. Subjects who are currently trying to stop smoking or considering stopping in the next two months.
9. Subject who are currently trying to stop the use of snus or considering stopping in the next two months.
10. Subjects who in the opinion of the Investigator should not participate in the study.
11. Subjects who were unwilling or unable to abide by the study requirements.

Date of first enrolment
20/01/2010

Date of final enrolment
01/08/2010

Locations

Countries of recruitment
United Kingdom

England

Sweden

Study participating centre
Chief Scientific Officer
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Sponsor information

Organisation
British American Tobacco (Investments) Ltd.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2013		Yes	No