

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

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<b>Registration date</b> 29/01/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/01/2013	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## 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

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

Principal Investigator:

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## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

Nicotine in plasma

## **Secondary outcome measures**

Sensory evaluation of oral tobacco products

## **Overall study start date**

20/01/2010

## **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/m<sup>2</sup> 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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

The study will be carried out at a single site in Sweden and is designed with 20 subjects.

**Key exclusion criteria**

1. Subjects who have a history of, or clinically active significant, medical disorders including:
  - 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**

England

Sweden

United Kingdom

**Study participating centre****Chief Scientific Officer**

Southampton

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## **Sponsor information**

**Organisation**

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**Sponsor type**

Not defined

**Website**

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

**ROR**

<https://ror.org/01znsh139>

## Funder(s)

**Funder type**

Industry

**Funder Name**

British American Tobacco (Investments) Ltd. (UK)

## 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="#">Results article</a>	results	01/01/2013		Yes	No