ISRCTN10158455 https://doi.org/10.1186/ISRCTN10158455

Human Cigarette Smoke Challenge Study

Submission date 18/04/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 23/05/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/06/2016	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is designed to help understand more about the changes that occur in blood and in the nose after smoking cigarettes. It is believed that this research may help develop and test new drugs to treat diseases caused by cigarette smoke. This will be assessed by observing changes in certain chemicals in the blood and nose, before and after smoking 2 cigarettes (Smokers Only) or sham/dummy cigarettes (Non-Smokers Only). In order to do this, blood and nasal samples will be taken at certain times throughout the study.

Who can participate?
Men and women aged 40 to 80 years in relatively good health . Specific criteria applies for each Group of subjects, with emphasis on the degree of lung function.
Group 1 will be participants who smoke and have moderate COPD
Group 2 will be participants who smoke but without evidence of COPD
Group 3 will be participants who have never smoked other than on an occasional basis and no cigarettes in the last year.

What does the study involve?
Volunteers in Groups 1 and 2 (smokers) will have up to 5 visits, up to 3 initial screening visits. On the last 2 visits, volunteers will smoke cigarettes under strictly controlled conditions in a ventilated body box, and have samples taken at very exact times. Volunteers in Group 3 (non-smokers) who have never smoked (other than on an occasional basis and no cigarettes in the last year) will have an initial screening visit followed by a single visit for a full day. The full day will involve inhaling through a sham or dummy cigarette, which does not involve any smoke inhalation.

What are the possible benefits and risks of participating?
Volunteers will not receive any direct medical benefit from participating in this study, but a potential benefit could be the detection of an unsuspected medical condition from tests performed. Drawing blood from a volunteers arm may cause mild discomfort, bruising or mild bleeding. All smokers are encouraged to give up smoking, and the team will be pleased to offer advice on this during the study. There is a small radiation risk to the smokers, since CT scan has a radiation dose of 5 times that of a chest X-ray. This is characterised by the Health Protection Agency (HPA) as being of low risk. You will not take any new drugs when participating in this study. There is a small risk from smoking four cigarettes during the study.

Where is the study run from?
Imperial Clinical Respiratory Research Unit, St Marys Hospital, London, UK

When is the study starting and how long is it expected to run for?
June 2012 to May 2013

Who is funding the study?
Sunovion Pharmaceuticals Europe Ltd (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
Dr Trevor Hansel

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R3101002

Study information

Scientific Title
An exploratory, non-drug, network biology study to develop a human in vivo model of acute cigarette smoke inhalation challenge in smokers with Chronic Obstructive Pulmonary Disease (COPD) and appropriate controls

Study objectives
To develop a novel cigarette challenge in vivo model incorporating full network biology analysis of transcriptomic, metabolomic and cytokine/chemokine changes in the nose and blood of

smokers with the Global Initiative for Chronic Obstructive Lung Disease (GOLD, www.goldcopd.org) Stage 2 COPD, healthy smokers with normal lung function and non-smokers, post cigarette smoking challenge or sham/dummy cigarette challenge (as applicable).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

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
Chronic Obstructive Pulmonary Disease / Healthy Smokers / Healthy Non-Smokers

Interventions
Group 1: Smokers with moderate COPD
Group 2: Smokers with no evidence of COPD
Group 3: Non smokers (have never smoked, other than on an occasional basis and no cigarettes in the last year)

During the two cigarette smoking challenge days, which will be conducted on two separate days (Study Day 1 and on any day between Study Days 4-10), all smokers i.e subjects in Groups 1 and 2, will undergo a two cigarette smoking challenge in a controlled environment. Subjects in both groups will have between 3 and 9 days to recover from procedures between both challenges. On Cigarette Challenge Days 1 and 2, all smokers i.e subjects from Groups 1 and 2, must have fasted and refrained from smoking from the previous evening prior to the scheduled challenges. They will then undergo a two cigarette smoking challenge in a controlled environment. These subjects will have two nasal mucosal scrape procedures and serial blood sampling both pre and post challenges in order to enable full network biology analysis of transcriptomic, metabolomic and cytokine/chemokine changes in the nose and blood.

Subjects in Group 3 (Non-Smokers) will undergo a Sham/Dummy cigarette challenge and the same procedures as outlined above, where applicable.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To develop a novel cigarette challenge in vivo model incorporating full network biology analysis of transcriptomic, metabolomic and cytokine/chemokine changes in the nose and blood of smokers with the Global Initiative for Chronic Obstructive Lung Disease (GOLD, www.goldcopd.org) Stage 2 COPD, healthy smokers with normal lung function and non-smokers, post cigarette smoking challenge or sham/ dummy cigarette challenge (as applicable).

Secondary outcome measures
1. To stimulate blood ex vivo from all groups to follow-up and validate the observations of the primary objective
2. To identify molecular biomarkers for COPD patients
3. To develop a cigarette smoking challenge model in COPD patients

Overall study start date
29/06/2012

Completion date
28/02/2014

Eligibility

Key inclusion criteria
1. All subjects (males and females) will be in relatively good health aged >=40 and <=80 years
2. Specific inclusion criteria apply for each Group of subjects i.e Groups 1-3, with emphasis on the degree of lung function
2.1. COPD (Group 1): In addition to the general inclusion criteria, Smokers with COPD must also have a documented history of moderate COPD (GOLD Stage 2) and be clinically stable and free from an acute exacerbation of COPD for 8 weeks prior to Study Day 1.
2.2. Healthy Smokers Without Evidence of COPD (Group 2): Healthy smokers without evidence of COPD, in addition to the general inclusion criteria, must also Smoke ≥ 5 cigarettes per day and have a ≥10 pack year smoking history. Other criteria apply.
2.3. Non-smoking Healthy Subjects (Group 3): Healthy non-smokers without evidence of COPD, in addition to the general inclusion criteria must never smoked (other than on an occasional basis and no cigarettes in the last year).
3. Subjects must be able to comply with all aspects of the protocol and able to give written informed consent to participate in the study

Participant type(s)
Mixed

Age group
Adult

Sex

Both

Target number of participants
24

Key exclusion criteria
1. All subjects will not have, or have had a history of, clinically significant neurological, gastrointestinal, renal, hepatic, cardiovascular, psychological, metabolic, endocrine, haematological or other major disorders
2. They will not have, or have had a history of, drug or alcohol abuse

Date of first enrolment
29/06/2012

Date of final enrolment
28/02/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Mary's Hospital
London
United Kingdom
W2 1NY

Sponsor information

Organisation
Sunovion Pharmaceuticals Europe Ltd (UK)

Sponsor details
Southside
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Sponsor type
Industry

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http://www.sunovion.eu/

ROR
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Funder(s)

Funder type
Industry

Funder Name
Sunovion Pharmaceuticals Europe 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