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Effects of carbon monoxide on nasal mucociliary clearance

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 22/09/2014	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0236169531

Study information

Scientific Title

Study objectives
To determine the effects of low concentrations of carbon monoxide gas on the motility of human nasal cilia cells.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective single-blinded 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 patient information sheet

Health condition(s) or problem(s) studied
Ear, Nose and Throat

Interventions
A steady flow of normal air (100 ml/min) is fed into one nostril; the other nostril is left unblocked so air can escape. Simultaneously, the subject breathes via the mouth into an oxygen mouthpiece so that the soft palate closes the mouth from the nasal cavity, and gas flows from one nostril to the other without being inspired into the lungs. This lasts for 10 minutes. The saccharine test is then used to measure the nasal mucociliary clearance time. A saccharine granule is placed in the nose at the same site in all subjects. The time required for the subject to taste the sweetness is measured. Oral only breathing is maintained during the saccharine test. The test is repeated with a 100 cc/min flow of low concentration CO gas (30 ppm) fed into the nostril. The subject is blinded and does not know which gas is fed into the nostril. The nostril into which the gas is fed into is randomised. The background ambient CO level is measured using a commercially available CO detector.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The mucociliary clearance time, measured as the time to taste the saccharin

Secondary outcome measures
No secondary outcome measures

Overall study start date
21/08/2005

Completion date
21/08/2006

Eligibility

Key inclusion criteria
Healthy adult volunteers between 18 and 40 years old. Volunteers will be recruited from amongst medical and nursing staff and students at St Georges Hospital, London. They will be personally approached by the principle investigator.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Added 21/07/2008: 26

Key exclusion criteria
1. Smokers
2. Subjects with a history of chronic respiratory or nasal disease
3. Symptomatic upper respiratory tract infection during the previous 4 weeks
4. Subjects who have taken systemic or topical steroids or anti-histamine therapy during the previous 4 weeks
5. Presence of significant mechanical intra-nasal deformity such as a septal deviation or bony spur
6. Children under 16 years old
7. Vulnerable groups including those with learning difficulty, mental illness and dementia
8. Pregnancy
9. Other conditions that increase risk are hyperthyroidism, obesity, bronchitis, asthma, pre-existing heart disease and alcoholism

Date of first enrolment
21/08/2005

Date of final enrolment
21/08/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Otolaryngology
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
St George's Healthcare NHS Trust (UK)

Funder Name
NHS R&D Support Funding (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