

Effects of carbon monoxide on nasal mucociliary clearance

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/09/2014	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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