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A study of the influence of pheromones on superosmia

Submission date 28/09/2007	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/09/2007	**Overall study status** Stopped	
Last Edited 16/01/2014	**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
N0274181493

Study information

Scientific Title

Study objectives
The aim of this study is to evaluate the whether pheromones can influence the occurrence of superosmia during an olfactory threshold test.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added September 2008: UCLH Committee (UK), ref 06/Q0505/10, 04/08/06 (Ethics Approval), 18 /05/07 (R&D Approval).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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: Superosmia

Interventions
The study will take place at the ENT departments of Leicester Royal Infirmary and the West Suffolk Hospital. One hundred subjects will be recruited from amongst hospital staff who consider themselves to have a 'normal' sense of smell and no active sino-nasal disease. The study will take the form of a single-blinded randomised controlled trial. Subjects selected will be invited to undergo a 15 minute smell test and examination of their nose. They will be tested with a computer-driven olfactometer which enables a quantitative threshold test to be performed for several odours: phenethyl alcohol (roses), eucalyptol (menthol), acetic acid (vinegar) and mercaptan (gas). These odours have been shown to represent distinct entities in an individuals sense of smell (1) and the test format has been validated in our previous work (2). The test involves the patient being seated in front of the olfactometer and the process of the test is explained to them by the researcher. At the voice prompts from the computer attached to the

olfactometer, they will be asked to deliver two puffs of air from the spout using the two buttons attached to the olfactometers valve. The puffs of air are paired, one being a blank, the other containing the odour and they will be asked to identify the odour repeatedly like this in a forced response format until they have defined a threshold.

Following this they will then be exposed to either a pheromone (delta4,16-androstadien-3-one for female subjects and 1,3,5,(10),16-estratetraen-3-ol for male subjects) or sterile water - 1cm3 of the solution will be placed on a mask and held in front of the subjects nose for 2 minutes. The substance applied to the mask will be determined by use of a closed envelope system. Subjects will be then retested for their olfactory thresholds using the technique described above. This whole process will take less than an hour and no further involvement will be required of the individual subjects.

1. Gaskin JA, Robinson A, Philpott CM, Goodenough PC, Murty GE. Are patients cross-sensitive to odours in parallel threshold tests Chemical Senses 2006
2. Philpott CM, Dhanji F, Wolstenholme CR, Goodenough PC, Clark A, Murty GE. Eucalyptol olfactory threshold testing with a computer driven olfactometer. Journal of Laryngology and Otology 2006

Updated 16/01/2014: The study did not proceed due to a lack of funds and personnel.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
pheromones

Primary outcome measure
Olfactory thresholds

Secondary outcome measures
No secondary outcome measures

Overall study start date
11/08/2008

Completion date
01/08/2009

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
Anyone who considers themselves to have a normal sense of smell.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
Number of participants: 100 total. 50 from West Suffolk.

Key exclusion criteria
People who are found to be hyposmic/anosmic (ie lacking in ability to detect odours at normal levels), people with sino-nasal disease, people unable to understand spoken English or who are mentally impaired.

Date of first enrolment
11/08/2008

Date of final enrolment
01/08/2009

Locations

Countries of recruitment
Canada

United Kingdom

Study participating centre
St Paul's Sinus Centre
Vancouver, BC
Canada
V6Z 1Y6

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
University Hospitals of Leicester NHS Trust Headquarters
Level 3, Balmoral Building
Leicester Royal Infirmary

Infirmary Square,
Leicester
England
United Kingdom
LE1 5WW

Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
West Suffolk Hospitals NHS Trust (UK), NHS R&D Support Funding

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