

A study of the influence of pheromones on superosmia

Submission date 28/09/2007	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/01/2014	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

Protocol serial number
N0274181493

Study information

Scientific Title

Study objectives

The aim of this study is to evaluate 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

Study type(s)

Treatment

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 individual's 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 olfactometer's 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 ($\delta^4,16$ -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 subject's 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(s)

Olfactory thresholds

Key secondary outcome(s))

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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

United Kingdom

Canada

Study participating centre**St Paul's Sinus Centre**

Vancouver, BC

Canada

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Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (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

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

