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Nasal hyper-reactivity in multiple chemical sensitivity and chronic fatigue syndrome: randomised double blind, placebo-controlled, cross-over, nasal challenge study to evaluate neural and vascular responsiveness

Submission date 12/09/2003	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 07/04/2011	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Peter Howarth

Contact details
IIR (RCMB), MP 810
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD
+44 023 8079 6990
p.h.howarth@soton.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0231117469

Study information

Scientific Title

Acronym
N?A

Study objectives
To evaluate and gain insight into nasal hyper-reactivity in multiple chemical sensitivity and chronic fatigue syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double blind, placebo controlled cross over design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions
Not provided at time of registration

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
1. Concentration at which challenge is discontinued
2. Nasal lavage inflammatory proteins pre and post
3. Magnitude of symptoms

Secondary outcome measures
Not provided at time of registration

Overall study start date
27/09/2002

Completion date
26/09/2007

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
36 subjects between age of 18 - 60 years, 12 of which are healthy controls.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
36

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
27/09/2002

Date of final enrolment
26/09/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
IIR (RCMB), MP 810
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Southampton University Hospitals NHS Trust (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