

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/04/2011	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
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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

IIR (RCMB), MP 810

Southampton

United Kingdom

SO16 6YD

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

Southampton University Hospitals NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration