# Double-blind, placebo-controlled crossover trial of inhaled oxygen in the treatment of acute cluster headache

Submission date	Recruitment status	Prospectively registered	
22/04/2007	No longer recruiting	☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
15/06/2007	Completed	[X] Results	
Last Edited	Condition category	Individual participant data	
10/12/2009	Nervous System Diseases		

## Plain English summary of protocol

Not provided at time of registration

### Contact information

#### Type(s)

Scientific

#### Contact name

**Prof Peter Goadsby** 

#### Contact details

Institute of Neurology Queen Square London United Kingdom WC1N 3BG

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

 ${\bf Clinical Trials. gov\ number}$ 

Secondary identifying numbers

CHO<sub>2</sub>

# Study information

#### Scientific Title

#### Acronym

CHAO2

#### **Study objectives**

Oxygen is a more effective treatment of acute cluster headache than air.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

The National Hospital for Neurology and Neurosurgery, approved on 3 March 2003 (ref: 01/N122)

#### Study design

Double-blind, placebo-controlled, cross-over randomised trial.

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

Treatment

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Cluster headache

#### **Interventions**

Treatment of acute cluster headache with inhaled air or oxygen. Each participant will be randomised to treatment sequence of either AB or BA, where A is oxygen and B is inhaled air.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

Proportion of patients pain free after 15 minutes of treatment comparing oxygen and air.

#### Secondary outcome measures

- 1. Rendering the patient pain free at 30 minutes
- 2. Reduction in pain scale at 15, 30, 45 and 60 minutes
- 3. Need for rescue medication from 15 minutes after treatment
- 4. Overall response to the treatment and overall functional disability
- 5. Effect on associated symptoms

#### Overall study start date

02/04/2003

#### Completion date

30/04/2007

# **Eligibility**

#### Key inclusion criteria

- 1. Active Cluster headache
- 2. Attack duration between 45 minutes and three hours

#### Participant type(s)

**Patient** 

#### Age group

**Not Specified** 

#### Sex

Both

#### Target number of participants

55

#### Key exclusion criteria

- 1. Pregnant and lactating women will be excluded
- 2. Patients with moderate to severe chronic obstructive pulmonary disease will be excluded as the high-dose high-flow oxygen may affect their hypoxic respiratory drive.
- 3. Patients who cannot tolerate the oxygen mask in the correct fitting will be excluded from the study

#### Date of first enrolment

02/04/2003

#### Date of final enrolment

30/04/2007

# Locations

#### Countries of recruitment

England

**United Kingdom** 

#### Study participating centre Institute of Neurology London United Kingdom WC1N 3BG

# Sponsor information

#### Organisation

BOC Ltd (UK)

#### Sponsor details

Chertsey Road Windlesham Surrey United Kingdom GU20

#### Sponsor type

Industry

#### Website

http://www.boc-gases.com/

#### ROR

https://ror.org/052v1zn95

# Funder(s)

#### Funder type

Industry

#### Funder Name

**BOC Gases (International)** 

# **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

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/12/2009		Yes	No