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

Submission date
22/04/2007

Recruitment status
No longer recruiting

Registration date
15/06/2007

Overall study status
Completed

Last Edited
10/12/2009

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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
CHO2

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