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Expiratory flow limitation and heliox breathing in resting and exercising chronic obstructive pulmonary disease (COPD) patients

Submission date 04/05/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/06/2009	**Overall study status** Completed	
Last Edited 11/07/2019	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Edgardo D'Angelo

Contact details
Dipartimento di Fisiologia Umana
via Mangiagalli 32
Milano
Italy
20133
-
edgardo.dangelo@unimi.it

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Expiratory flow limitation and heliox breathing in resting and exercising chronic obstructive pulmonary disease (COPD) patients: a randomised double-blind cross-over trial

Study objectives
The effect of heliox (80% He, 20% O2) administration on breathing patterns and exercise capacity in patients with chronic obstructive pulmonary disease (COPD) is controversial. The objective of this study is to assess if tidal expiratory flow limitation affects the mechanical response of the respiratory system to heliox breathing during non-fatiguing exercises in patients with COPD. Tidal expiratory flow limitation, inspiratory capacity, breathing pattern and dyspnoea sensation will be assessed in stable patients during air and heliox breathing at rest and at 1/3 and 2/3 maximal work rate.

Previous results obtained with heliox in COPD patients at rest suggest that tidal expiratory flow limitation could play an important role in the response to heliox administration. So, our study will be focused on assessing if tidal expiratory flow limitation affects the mechanical response of the respiratory system to heliox breathing during non-fatiguing exercises in patients with COPD in basal condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee (Comitato Etico Azienda Ospedaliera San Paolo) approved on the 24th January 2007 (ref: 599 CE/MA/)

Study design
Randomised double-blind cross-over trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions

1. An incremental exercise test on a cycle ergometer while breathing ambient air
2. Breathing air for 10 minutes and then equilibration with heliox (20% O2, 80% He), both at rest and while cycling at 1/3 and 2/3 max for 6 - 8 minutes at each work level, measurements were taken when a quasi-steady breathing pattern had established. The test sequence was randomised.
3. Both at rest and during exercise, 4 - 6 negative expiratory pressure (NEP) tests were performed, followed by maximal inspirations to assess inspiratory capacity (IC), a reliable and commonly used procedure

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Heliox

Primary outcome measure
To compare the ventilatory response to heliox administration in expiratory flow-limited and non flow-limited COPD patients both at rest and during normal, non-fatiguing physical activities.

Secondary outcome measures
1. Dyspnoea
2. Flow limitation
3. Forced expiratory volume in one second (FEV1)
4. Inspiratory capacity (IC)
5. Forced volume capacity (FVC)

Overall study start date
01/02/2007

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Stable COPD patients with stable airway obstruction with any level of forced expiratory volume in one second (FEV1) value expressed of predicted
2. Male or female patients, 40 years of age or older
3. Patients must be current or ex-smokers with a smoking history of more than 10 pack years
4. Patients must be to able to perform technical acceptable pulmonary function tests and must be able to perform an incremental exercise test on a cycle ergometer

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
25

Total final enrolment
26

Key exclusion criteria
1. Patients with a signficant disease other than COPD that conditioning a risk for exercise testing (this is evaluated by medical investigators)
2. Patients with a history of asthma
3. Patients with a diagnosis of paroxysmal tachycardia, atrial fibrillation and recent history of myocardial infarction (less of 2 years)
4. Known active tubercolosis
5. History of cystic fibrosis
6. Pregnant women
7. Patients aged more than 85 years old

Date of first enrolment
01/02/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Italy

Study participating centre
Dipartimento di Fisiologia Umana
Milano
Italy
20133

Sponsor information

Organisation
University of Milan (Univrsità degli Studi di Milano) (Italy)

Sponsor details

Via Festa del Perdono, 7
Milano
Italy
20122
+39 (0)2 503 111
a@b.com

Sponsor type
University/education

Website
http://www.unimi.it/

ROR
https://ror.org/00wjc7c48

Funder(s)

Funder type
Government

Funder Name
Ministry of Education, University and Scientific Research (Ministero dell'Istruzione, dell'Università e della Ricerca Scientifica) (MIUR) (Italy)

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	31/12/2009	11/07/2019	Yes	No