# Randomised double-blind comparison of handheld inhalers versus electric compressors and nebulisers, for domiciliary high-dose bronchodilator treatment in severe stable chronic obstructive pulmonary disease (COPD)

Recruitment status	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	[] Individual participant data
Respiratory	Record updated in last year
	No longer recruiting  Overall study status  Completed  Condition category

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Kate Hill

#### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

#### ClinicalTrials.gov number

Secondary identifying numbers ND0020 T331

## Study information

#### Scientific Title

Randomised double-blind comparison of hand-held inhalers versus electric compressors and nebulisers, for domiciliary high-dose bronchodilator treatment in severe stable chronic obstructive pulmonary disease (COPD)

#### **Study objectives**

Approximately 200,000 people in the Yorkshire Region have COPD of varying degrees of severity. A recent published regional review has shown that more than 2000 of the more severely disabled patients are currently treated at home with high dose bronchodilators using nebulisers and compressors. This represents a £20k capital cost, an approximate annual £20k servicing cost, and an annual drug bill of £2m. The regional review has shown that this expensive treatment is often introduced without adequate assessments. Hand-held inhalers may be more efficient and cheaper. Projected drug costs if hand held inhalers were used for the usual combination of bronchodilator drugs for such patients in equivalent doses would be approximately £700k per annum with a potential saving to the Health Authorities of more than a million pounds per annum.

Similarly, regular use of newer-generation nebulisers, which are more efficient, might result in a saving of half the drug costs, again without any compromise in patient benefit. Before purchasers can recommend either a trial of high dose hand-held inhalers or the use of newer-generation nebulisers to achieve these savings, it is necessary to show in a controlled double-blind study that patient benefit from equipotent doses in the three systems (current nebuliser treatment versus hand-held treatment versus new-generation nebuliser treatment) are equivalent. This study will provide evidence allowing purchasers to make such judgments. From the patients point of view, the benefit from using hand-held inhalers rather than electric compressors and nebulisers is that the treatment is less complex, taking 15 minutes per day rather than one hour per day to use and would allow people to travel, and not to rely on emergency back-up and service arrangements.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

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

Chronic obstructive pulmonary disease

#### **Interventions**

Current nebuliser treatment versus hand-held treatment versus new-generation nebuliser treatment

## Intervention Type

Other

#### **Phase**

**Not Specified** 

#### Primary outcome measure

Quality of life measured by SGRQ (St George's Respiratory Questionnaire)

#### Secondary outcome measures

Not provided at time of registration

## Overall study start date

01/01/1995

#### Completion date

31/03/1995

## **Eligibility**

#### Key inclusion criteria

Patients with COPD

## Participant type(s)

**Patient** 

#### Age group

**Not Specified** 

#### Sex

Both

## Target number of participants

Not provided at time of registration

## Key exclusion criteria

Does not match inclusion criteria

#### Date of first enrolment

01/01/1995

#### Date of final enrolment

31/03/1995

## Locations

#### Countries of recruitment

England

United Kingdom

# Study participating centre Academic Unit of Psychiatry and Behavioural Sciences

Leeds United Kingdom LS2 9LT

# Sponsor information

#### Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

## Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

## Sponsor type

Government

#### Website

http://www.doh.gov.uk

# Funder(s)

## Funder type

Government

#### Funder Name

NHS Executive Northern and Yorkshire (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