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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)

Submission date
23/01/2004

Registration date
23/01/2004

Last Edited
23/10/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Respiratory

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/03/1995

Eligibility

Key inclusion criteria
Patients with COPD

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

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
United Kingdom

England

Study participating centre
Academic Unit of Psychiatry and Behavioural Sciences
Leeds
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LS2 9LT

Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration