ISRCTN13825248 https://doi.org/10.1186/ISRCTN13825248

A single blind randomised controlled trial to determine the effectiveness and cost utility of manual chest physiotherapy techniques in the management of infective exacerbations of Chronic Obstructive Pulmonary Disease

Submission date
14/03/2005

Recruitment status
No longer recruiting

Registration date
16/03/2005

Overall study status
Completed

Last Edited
29/10/2012

Condition category
Respiratory

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

Plain English summary of protocol
http://www.hta.ac.uk/1416

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 03/13/06

Study information

Scientific Title

Acronym
MATREX

Study objectives
This study proposes to look exclusively at COPD and compare a group of patients who do receive a chest physiotherapy intervention of manual techniques with a group of patients who receive no manual intervention but are given an information sheet, and to follow up all patients for one year.

Please note that, as of 11/05/2009, the anticipated start and end dates have been updated from 01/12/2004 and 31/08/2008 to 01/03/2005 and 30/04/2009, respectively.

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease (COPD)

Interventions

Please note that, as of 10 January 2008, the anticipated start and end dates of this trial have been updated from 1 December 2004 and 31 August 2008 to 1 March 2005 and 30 April 2009, respectively.

Interventions:

Intervention arm:
Participants will receive the respiratory manual techniques of percussion, vibrations and chest shaking. A standard treatment protocol manual will be followed by all the participating hospitals. This manual will be developed with the clinical staff involved in order to represent current practice and optimise compliance. Treatment will be applied with the patient positioned according to an agreed protocol for optimal drainage of secretions. The chest will be percussed whilst the patient performs thoracic expansion exercises and vibrations and shaking will be applied on expiration. Treatment will be interspersed with periods of relaxed abdominal breathing, breathing control. Participants will also be given an information sheet giving advice on positioning, managing cough and mobilisation. The content, number and duration of treatments will be at the discretion of the physiotherapist applying treatment, within the bounds set by the manual and will be varied according to clinical need. This information will be recorded. Oxygen saturation will be monitored and recorded during treatment. Once the patient has returned to his/her normal stable saturation, monitoring will stop. Sputum produced in each 24 hour period will be collected and its volume measured throughout each hospital admission.

Control arm:
Participants will receive no manual chest physiotherapy. They will be given the same information sheet giving advice on positioning, managing coughing and mobilisation by a physiotherapist. 24 hour sputum volumes will be measured as for the intervention group. For patients in the control arm who show severe deterioration due to sputum retention, additional physiotherapy including manual techniques will be permitted. Such movement between trial arms will be monitored closely. Movement between arms will occur where there is clear clinical evidence of sputum retention (Auscultation/chest x-ray [CXR] evidence) in conjunction with a pH of less than 7.26, a rising CO2 in patients already receiving supportive treatment and controlled oxygen therapy. The primary analysis will be intention to treat. A per protocol analysis will be performed as a secondary analysis, with adjustment for baseline differences.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quality of Life (St Georges Respiratory Questionnaire) at baseline, six weeks, three months, six months and one year post intervention.

Secondary outcome measures
Quality of life, breathlessness and exercise tolerance:
1. Breathlessness, Cough and Sputum Scale (QOL)
2. EuroQol five dimensional instrument (EQ-5D)
3. Sputum volume and oxygen saturation during hospitalisation
4. Total number of days spent in hospital during 12 months period
5. Marginal cost-utility ratio for manual versus no manual chest physiotherapy

Overall study start date
01/03/2005

Completion date
30/04/2009

Eligibility

Key inclusion criteria
Patients admitted to participating hospitals with infective exacerbations of COPD.

Inclusion Criteria:
1. Diagnosis of COPD as defined by the British Thoracic Society; namely
a. A forced expiratory volume in the first second (FEV1) of <80% of the predicted value, which is predominantly irreversible
b. Signs and symptoms of cough, breathlessness and +/- wheeze
c. In more severe disease there may be cyanosis and peripheral oedema

2. An infective exacerbation as set out by the British Thoracic Society; namely
a. A worsening of previous stable condition, a new respiratory event or complication imposed upon established COPD
b. Signs and symptoms of increased wheeze, dyspnoea, sputum volume and purulence, chest tightness and fluid retention

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
550

Key exclusion criteria
1. Cognitive impairment, rendering patients unable to give fully informed consent

2. Contraindications to the use of manual techniques; namely
a. Osteoporosis
b. Frank haemoptysis
c. Bronchial hyper-reactivity
d. Known respiratory system malignancy

3. No evidence of excess sputum production after examination (i.e. the patient does not report excess secretions and no signs of excess secretions on auscultation)

Date of first enrolment
01/03/2005

Date of final enrolment
30/04/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Allied Health Professions
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation
University of East Anglia (UK)

Sponsor details
-
Norwich
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Sponsor type
University/education

Website
http://www1.uea.ac.uk/cm/home

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2010		Yes	No
Results article	results	02/07/2012		Yes	No