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ADOPT: Airways Disease-Optimisation of Pharmaco-Therapy in lung cancer

Submission date 25/11/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 28/02/2011	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 03/09/2018	**Condition category** Respiratory	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-inhalers-relieve-breathlessness-lung-cancer-adopt

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ADOPT Version 1.2.2

Study information

Scientific Title

Prospective randomised controlled trial to investigate the effectiveness of inhalers for the relief of breathlessness in patients with lung cancer and chronic obstructive pulmonary disease (COPD)

Acronym
ADOPT

Study objectives
We hypothesise that undiagnosed COPD is common in breathless patients with lung cancer and identification and optimisation of their treatment with inhaled therapy (locally-acting bronchodilators and corticosteroids) may improve breathlessness beyond that achievable with best supportive care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Research Ethics Committee, 13/10/2010, ref: 10/H1102/66

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Patients will be randomised to one of two groups
1. Intervention group:
1.1. Ventolin Evohaler 100 micrograms, 2 inhalations 4 times a day
1.2. Spiriva 18 micrograms one inhalation a day
1.3. Seretide Accuhaler 50 microgram/500 microgram inhaler one inhalation twice a day.
These therapies in combination are the mainstay of symptomatic management in patients with COPD. Each patient will remain on study medication for 4 weeks.
2. Control group: Treatment as usual

Intervention Type
Drug

Phase
Not Applicable

Primary outcome(s)
Proportion of patients who have a ≥ 2 point change in their Visual Analogue Scale (VAS) for dyspnoea at 4 weeks

Key secondary outcome(s))
1. Six-minute walk test (6MWT) at 2 and 4 weeks
2. Forced expiratory volume in 1 second (FEV1) at 2 and 4 weeks
3. Peak expiratory flow rate (PEFR) at 2 and 4 weeks
4. Quality of life using the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire + Lung cancer module (EORTC C-30 + L13) at 4 weeks
5. Level of physical activity using the St Georges Respiratory Questionnaire (SGRQ) activity scale at 4 weeks
6. To investigate and describe the relationship of breathlessness and obstructive lung disease (% predicted FEV1) in patients with lung cancer
7. To investigate and describe any relationship between breathlessness and the position of the tumour in relation to the bronchial tree (large airway/central Vs peripheral)

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Male or female, age > 35 years
2. Diagnosis of non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC) or mesothelioma
3. Diagnosis of COPD
4. Subjective dyspnoea of visual analogue score (VAS) ≥ 4

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Involvement in any other studies of breathlessness
2. Reversible causes of breathlessness
3. Patients receiving radiotherapy, chemotherapy, biological therapy or surgery. Or a plan to commence these treatments within 4 weeks
4. Current use of bronchodilators either inhaled or oral (aminophyline, methyxanthines) except for short-acting bronchodilators
5. Recent change to oral corticosteroid therapy dose (within 1 week of randomisation)
6. Current use of beta-blockers for any reason
7. Current use of anti-cholinergic containing drugs
8. Current use of potent CYP30 inhibitors (ritonavir, ketoconazole, itraconazole)
9. Patients with the following conditions:
9.1. Asthma
9.2. Severe cardiovascular disorders (myocardial infarction within 6 week)

9.3. Heart rhythm abnormalities
9.4. Thyrotoxicosis
9.5. Uncorrected hypokalaemia
9.6. Glaucoma
9.7. Prostate problems
9.8. Patients with difficulty passing urine
9.9. Renal failure
9.10. TB (current or previous)
10. Pregnancy
11. Patients with hypersensitivity to any of the study drugs, lactose allergy

Date of first enrolment
28/01/2011

Date of final enrolment
23/06/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Marsden Hospital
Down's Road
Sutton
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Study participating centre
Royal Marsden Hospital
203 Fulham Road
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Sponsor information

Organisation
The Royal Marsden NHS Foundation Trust (UK)

ROR
https://ror.org/0008wzh48

Funder(s)

Funder type
Government

Funder Name
The Royal Marsden NHS Foundation Trust (UK) - Alan J Lerner Lung Research Fund

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date .

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version V2	04/07/2013	04/12/2017	No	Yes