

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

Contact name

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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

Primary study design

Interventional

Study design

Randomised controlled trial

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 (aminophylline, methylxanthines) 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

United Kingdom

SM2 5PT

Study participating centre

Royal Marsden Hospital

203 Fulham Road

Chelsea

London

United Kingdom

SW3 6JJ

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