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Randomised evaluation of stents to open restricted airways in patients with centrally placed non-small cell lung cancer

Submission date 21/10/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 21/10/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 26/10/2022	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-stents-to-relieve-breathlessness-for-non-small-cell-lung-cancer-restore-air

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT01003522

Secondary identifying numbers
6064

Study information

Scientific Title
Randomised Evaluation of STents to Open REstricted AIRways in patients with centrally placed non-small cell lung cancer: a multicentre randomised interventional phase III treatment trial

Acronym
RESTORE-AIR

Study objectives
This study intends to build on a previous small pilot study which showed good improvement in breathlessness in lung cancer patients with the insertion of a bronchial stent. We wish to compare the improvement in dyspnoea with or without a bronchial stent at 2 weeks. We wish to assess if an improved clinical state improves outcomes of tumour specific therapy in these patients. Subjective assessment of breathlessness will be followed, but also the use of rescue medication (such as opioids), and objective measures of pulmonary function including the 6 minute walking distance (6MWD), arterial blood gas analysis and spirometry (where possible).

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC for Wales, 03/04/2008, ref: 08/MRE09/6

Study design
Multicentre randomised interventional phase III treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Lung Cancer; Disease: Lung (non-small cell)

Interventions
Bronchial stent insertion versus no stent.

Follow up length: 3 months
Study entry: single randomisation only

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Improvement in dyspnoea, measured at 2 weeks

Secondary outcome measures
No secondary outcome measures.

Overall study start date
13/10/2008

Completion date
01/03/2010

Eligibility

Key inclusion criteria
1. Able to give informed written consent in the English language
2. Male or female, aged greater than 18 years
3. Able and willing to attend St George's Hospital/Royal Marsden Hospital (RMH) for stent insertion (if allocated) and documentation of 6-minute walk distance (6MWD)
4. Willing to re-attend for follow-up and 6MWD at St George's Hospital/RMH 2 weeks later (all patients)
5. Diagnosis of non-small cell lung cancer (NSCLC) with centrally placed tumour with some degree of airway obstruction from information from bronchoscopy or computed tomography (CT) scan
6. Eastern Cooperative Oncology Group (ECOG) performance status 0 - 3

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 60; UK sample size: 60

Total final enrolment
21

Key exclusion criteria
1. Relative contraindications to stenting, e.g. bleeding abnormality or relative anticoagulation problems
2. Pregnancy
3. Surgically resectable disease

Date of first enrolment
13/10/2008

Date of final enrolment
01/03/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Marsden Hospital
Downs Road
Sutton
United Kingdom
SM2 5PT

Sponsor information

Organisation
The Royal Marsden Hospital NHS Foundation Trust (UK)

Sponsor details
Fulham Road
London
England
United Kingdom
SW3 6JJ

Sponsor type
Hospital/treatment centre

Website

http://www.royalmarsden.nhs.uk

ROR
https://ror.org/0008wzh48

Funder(s)

Funder type
Research organisation

Funder Name
Marie Curie Fellowship (UK)

Funder Name
National Cancer Research Institute

Alternative Name(s)
NCRI

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Plain English results	26/10/2022	No	Yes