

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 26/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

ClinicalTrials.gov (NCT)

NCT01003522

Protocol serial number

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

Primary study design

Interventional

Study design

Multicentre randomised interventional phase III treatment trial

Study type(s)

Treatment

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(s)

Improvement in dyspnoea, measured at 2 weeks

Key secondary outcome(s)

No secondary outcome measures.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

Royal Marsden Hospital

Downs Road

Sutton

United Kingdom

SM2 5PT

Sponsor information

Organisation

The Royal Marsden Hospital NHS Foundation Trust (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

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