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

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

Contact name

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Contact details

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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?

<u>Plain English results</u> 26/10/2022 No Yes