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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
21/10/2010		Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
21/10/2010		Results		
Last Edited		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

Ms Alison Norton

#### Contact details

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# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

NCT01003522

Protocol serial number

# 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

## 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

Αll

#### 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