A study of Rehabilitation in patients taking part in the Operated Lung Cancer Programme in comparison to the non intervention group

Submission date	Recruitment status No longer recruiting	Prospectively registered		
27/05/2011		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
27/05/2011	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
25/02/2019	Cancer			

Plain English summary of protocol

http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-at-rehabilitation-programme-for-people-having-lung-cancer-surgery

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

9448

Study information

Scientific Title

A study of rehabilitation in patients taking part in the operated lung cancer programme in comparison to the non intervention group

Acronym

ROC

Study objectives

The study aims to examine whether a rehabilitation programme that identifies potential surgical candidates several weeks before surgery and optimises their physical status, prepare them for the inpatient journey and support their recovery after surgery, reduces:

- 1. In patient length of stay
- 2. Reduced rate of Pulmonary Complication (PPC)
- 3. Reduced ITU and HDU admissions
- 4. Increased patient quality of life
- 5. Deliver cost savings

Ethics approval required

Old ethics approval format

Ethics approval(s)

First MREC approval date 21/07/2010, ref 10/H1208/41

Study design

Non-randomised interventional and Observational qualitative trial

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Lung cancer (small cell & non-small cell)

Interventions

- 1. Rehabilitation for Operated lung Cancer (ROC) programme
- 2. Pulmonary rehabilitation
- 3. Smoking cessation
- 4. Dietary advice
- 5. Patient self-management
- 6. Follow up length: 5 month(s)
- 7. Study entry: registration only

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

- 1. Reduced inpatient length of stay
- 2. Timepoint(s): discharge from hospital

Secondary outcome measures

- 1. Increased patient quality of life, timepoint(s): 5 months from surgery
- 2. Reduced ITU and admissions, timepoint(s): discharge
- 3. Reduced rate of Pulmonary Complication (PPC), timepoint(s): discharge

Overall study start date

01/04/2011

Completion date

01/04/2016

Eligibility

Key inclusion criteria

- 1. All Patients undergoing curative lung resections for lung cancer
- 2. Patients that are equal to 18 years old or over
- 3. Patients willing to give consent
- 4. Patients treated by Heart of England Foundation NHS Trust (Heartlands and Solihull Hospital not Good Hope Hospital
- 5. Patients treated by Worcestershire Acute Hospitals Trust (Worcester Royal Hospital)
- 6. Target gender: male & female
- 7. Lower age limit 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Total of 1275 patients will be recruited into the study, 850 control and 425 case patients over 5 years

Key exclusion criteria

Patients referred from

- 1. Heart of England Foundation NHS Trust, Good Hope Hospital
- 2. Worcestershire Acute Hospitals NHS Trust, Redditch Hospital
- 3. University Hospitals Birmingham Foundation NHS Trust
- 4. Sandwell and West Birmingham Hospitals NHS Trust
- 5. Gloucestershire Hospitals NHS Foundation NHS Trust
- 6. Hereford Hospital NHS Trust
- 7. Walsall Hospitals NHS Trust

Date of first enrolment

01/04/2011

Date of final enrolment

01/04/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Critical Care MIDRU

Birmingham United Kingdom B9 5SS

Sponsor information

Organisation

Heart of England NHS Foundation Trust

Sponsor details

3 Bordesley Green East Bordesley Green Birmingham England United Kingdom B9 5SS

Sponsor type

Hospital/treatment centre

Website

http://www.heartofengland.nhs.uk/

Funder(s)

Funder type

Charity

Funder Name

The Health Foundation (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2013		Yes	No
Results article	results	01/05/2019	25/02/2019	Yes	No