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Psychological distress following rapid diagnosis of lung cancer

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 05/12/2014	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0054119936

Study information

Scientific Title
Psychological distress following rapid diagnosis of lung cancer

Study objectives
Does rapid diagnosis of lung cancer increase psychological morbidity and are patient expectations of care and their experience of treatment related to their psychological state?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Cancer: Lung

Interventions
A single centre cross-sectional study aims to identify levels of anxiety, depression and distress in patients following diagnosis of lung cancer. 104 Patients will be randomly selected for inclusion from the Rapid Access Lung Shadow Clinic over a period of 6 months. Once informed consent has been obtained interviews will be conducted by specialist nurses in patient's own homes. Four brief psychometric tests will be performed, Becks Depression Inventory, Self-Trait Anxiety Inventory, The Ways of Coping Questionnaire and the Brief Symptom Inventory. A second and third interview repeating the psychometric tests will be conducted within 7 and 30 days of diagnosis respectively.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The identification of levels of anxiety, depression, and distress as indicators of psychological morbidity will inform and allow the planning of strategic initiatives to support future resource allocation, interprofessional working and improved clinical outcomes.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2003

Completion date
01/12/2003

Eligibility

Key inclusion criteria
104 patients will be randomly selected for inclusion from the Rapid Access Lung Shadow Clinic over a period of 6 months. On average 12 patients per week are seen at this clinic and it is assumed that two out of every three patients meet the criteria. There is a 95% probability that the mean state anxiety score of this sample will be within +- 3 points of the population mean.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
104

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2003

Date of final enrolment
01/12/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Liverpool
Liverpool
United Kingdom
L69 3GB

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Cardiothoracic Centre Liverpool NHS Trust (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