A randomised controlled trial of a patient-held quality of life record in patients with inoperable lung and oesophageal cancer

Submission date	Recruitment status No longer recruiting	Prospectively registered	
01/06/2007		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
25/06/2007	Completed	[X] Results	
Last Edited	Condition category	Individual participant data	
17/08/2012	Cancer		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Study objectives

To determine if patient held Quality of Life (QoL) tools improve the quality of care and patient quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Office of Resarch Ethics Committees Northern Ireland (ORECNI) on 30/11/2004 (ref: 04/NIR01/77)

Study design

A multi-centred randomised controlled trial.

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Lung and oesophageal cancer

Interventions

Patients receive a QoL diary which consists of a core questionnaire (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients [EORTC QLQ C-30]) with a Lung (LC-13) or Oesophageal (OES-18) cancer module, in the form of an A5 booklet, which they complete weekly. Patients are encouraged to share their diary with health professionals involved in their care.

The duration of treatment was four months, and at the end of this period outcomes were collected for both arms of the treatment, therefore there is no additional follow-up period for this trial.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The primary outcome is QoL, measured through two questionnaires:

- 1. Functional Assessment of Cancer Therapy General questionnaire (FACT-G) with lung and oesophageal modules, measured at the end of month two and month four following recruitment
- 2. Palliative care quality of life index, measured at the end of month two and month four following recruitment

Key secondary outcome(s))

Secondary outcomes include:

- 1. Indices of patient satisfaction, measured at the end of month two and month four following recruitment
- 2. Impact on carers, measured at the end of month two and month four following recruitment
- 3. Measures of communication, measured at the end of month two and month four following recruitment
- 4. Multi-disciplinary nature of patient management, measured at the end of month two and month four following recruitment

Completion date

01/01/2007

Eligibility

Key inclusion criteria

- 1. Inoperable lung and oesophageal cancer
- 2. World Health Organisation (WHO) performance status of zero to two
- 3. No cognitive impairment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

- 1. Surgically resectable patients
- 2. WHO performance status of 3+
- 3. Cognitively impaired patients

Date of first enrolment

01/01/2005

Date of final enrolment

01/01/2007

Locations

Countries of recruitment

United Kingdom

Northern Ireland

Study participating centre
Epidemiology and Public Health
Belfast
United Kingdom
BT12 6BJ

Sponsor information

Organisation

Queen's University Belfast (UK)

ROR

https://ror.org/00hswnk62

Funder(s)

Funder type

Government

Funder Name

Research and Development Office of Northern Ireland (UK) (ref: EAT/2551/03)

Results and Publications

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	feasibility results	01/12/2008	Yes	No
Results article	results	01/01/2009	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes