

# **SPECIAL: Standard or Palliative Care in Advanced Lung Cancer - Does early referral of patients with metastatic non-small cell lung cancer to UK specialist palliative care services make a difference in their quality of life or survival?**

<b>Submission date</b> 02/06/2015	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 17/06/2015	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/08/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## **Plain English summary of protocol**

Not provided at time of registration

## **Study website**

Pending

## **Contact information**

### **Type(s)**

Public

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Scientific

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

HTA 11/108/06; sponsor's ref : STH17019; University of Birmingham ref : LU3006

## **Study information**

**Scientific Title**

A phase III randomised trial, with integral feasibility stage, to assess changes in quality of life and survival in patients being referred for early than versus standard specialist palliative care on being diagnosed with stage IV non-small cell lung cancer.

**Acronym**

SPECIAL

**Study objectives**

Palliative care services in the UK have have traditionally been provided for patients with advanced cancer by local and national independent charitable organisations. Recent progress in anticancer treatments means that increasingly patients with advanced disease may still be receiving active interventions into the late stages of disease. Thus it is important for both the National Health Service and other providers to undertake research into new models of care in advanced cancer, in which anticancer treatment and patient/family-directed supportive and palliative care services are simultaneously provided.

To help direct supportive and palliative care interventions, the National Cancer Action Team has recommended that all patients with cancer should receive Holistic Needs Assessment (HNA) at

key points of their trajectory from diagnosis, after primary treatment, through continuing disease into end of life care or into survivorship.

As patients with advanced non-small cell lung cancer (NSCLC) often have a high symptom burden at diagnosis this patient group is in particular need of HNA at the point of diagnosis as well as through their ongoing care. Holistic needs include not only physical symptoms but also psychological, social, spiritual, financial issues; problems with independent living; concerns about treatments and side-effects; and information needs. Many services are not yet using any formal means of assessing holistic needs though there is a range of HNA tools available with the Distress Thermometer/Concerns Checklist or the Sheffield Profile for Assessment and Referral for Care (SPARC) most commonly used in the UK (Ahmedzai et al., 2008).

A single-centre study in USA found that patients with advanced NSCLC randomised to early palliative care had improved quality of life parameters and also achieved a longer survival time compared to patients who had palliative care according to standard procedures (Temel et al, 2010). The SPECIAL trial has been designed to address the question of whether early referral to palliative care services in the UK achieves the same range of benefits as those observed in the US study, given that the availability, structure and funding of palliative care are so different in the two countries. It further asks the question whether a formal holistic needs assessment enhances the referral to palliative care.

#### References :

Ahmedzai SH, K.G., Rogers E, Noble B, SPARC: a holistic screening questionnaire for palliative and supportive care needs. J Palliat Care 2008. 24(3): p. 194-195.

Temel, J.S., et al., Early palliative care for patients with metastatic non-small-cell lung cancer. N Engl J Med, 2010. 363(8): p. 733-42.

More details can be found at <http://www.nets.nihr.ac.uk/projects/hta/1110806>

Protocol can be found at [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0005/117428/PRO-11-108-06.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0005/117428/PRO-11-108-06.pdf)

#### **Ethics approval required**

Old ethics approval format

#### **Ethics approval(s)**

UK REC North West – Greater Manchester (West), 22/05/2015, ref: 15/NW/0324

#### **Study design**

Phase III randomised controlled trial with integral feasibility stage (non-randomised)

#### **Primary study design**

Interventional

#### **Secondary study design**

Randomised controlled trial

#### **Study setting(s)**

Hospital

#### **Study type(s)**

Quality of life

## **Participant information sheet**

Patient's and Carers' information sheet is not available in web format; please use the contact details below to request the relevant patient information sheet

## **Health condition(s) or problem(s) studied**

Stage IV non-small cell lung cancer; specialist palliative care

## **Interventions**

Feasibility study :

All patients will be asked to complete a Sheffield Profile for Assessment and Referral for Care (SPARC) holistic needs questionnaire (a copy of the last form completed by the patient to be sent with the referral letter to specialist palliative care (SPC), if and when this occurs).

Randomised trial:

Study arms:

Arm A : Standard of care (i.e., standard referral to SPC, if patient is willing)

Arm B : sub-randomisation

Arm B1 : Early SPC referral + standard of care

Arm B2 : Early SPC referral + standard of care + SPARC assessment

## **Intervention Type**

Other

## **Primary outcome measure**

Feasibility study :

1. The number of potentially eligible patients and the proportion consenting to registration in the three participating centres, and to evaluate adequate acceptance rate for patient willingness to be randomised

2. Patient pathway planning and scoping for Randomised Controlled Trial (RCT) adaptation

3. Feasibility of using quality of life (QoL) and resource use questionnaires

To inform design for large scale RCT.

Randomised trial:

To compare the two treatment arms in terms of the two co-primary outcome measures:

1. Global Health Status Score (GHSS) at 3 months after trial entry

2. Quality-adjusted survival time (QAS) over 6 months (also referred to as Quality Adjusted Life Years [QALY])

## **Secondary outcome measures**

Randomised trial:

1. Overall survival: defined as the time from randomisation to death (due to any cause) or to date last seen for those not known to have died

2. Anxiety/depression: as measured using the patient-completed HADS questionnaire at baseline, 3 and 6 months

3. Pain: as measured using the EORTC QLQ-C30 and –LC13 questionnaires at baseline and subsequent monthly (or three-weekly, treatment regime dependent) clinic visits

4. Health Economics, Cost-effectiveness and Resource Use:

4.1. Number of days spent in hospital/hospice: obtained from patient records. Duration defined as time from admission to discharge

4.2. Use, or not, of medical interventions in last month of life: details to be collected from patient records. The patient subgroup will be defined as those for which death was observed

- 4.3. Intensive Therapy Unit (ITU) admission: the number of patients admitted, the frequency of duration of visits will be obtained from patient records. Duration is defined as the time from admission to discharge from ITU
- 4.4. Use of Cardio Pulmonary Resuscitation (CPR): obtained from patient records
5. Quality of life: to be assessed using EQ-5D-5L and EORTC QLQ-C30, -LC13 and -BM22 questionnaires at baseline and subsequent monthly (or three-weekly, treatment regime dependent) clinic visits
6. Memory and cognitive ability: will be assessed for consenting participants using the Montreal Cognitive Assessment (MoCA) at baseline, 3 and 6 months
7. Modified Glasgow Prognostic Score (mGPS): will be assessed from blood albumin and CRP results at baseline, 3 and 6 months

Secondary outcomes pertaining to family care-givers include:

1. Health Survey: assessment using the SF-12® at baseline and subsequent visits to the clinic corresponding with the patient participant's visits
2. Satisfaction with patient participant's end of life care: assessed using the CODE™ instrument, completed by the carer (if willing) approximately 3 months post bereavement

**Overall study start date**

01/03/2014

**Completion date**

03/03/2016

**Reason abandoned (if study stopped)**

Participant recruitment issue

## **Eligibility**

**Key inclusion criteria**

Patients :

1. Any adult ( $\geq 18$  years) patient with newly diagnosed stage IV non-small cell lung cancer, with histologically confirmed diagnosis
2. ECOG performance score 0-3

Carers:

Must be caring for a patient participant of the trial.

NB. A patient's involvement in the trial is not dependent upon having a carer willing and able to take part also.

**Participant type(s)**

Mixed

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Feasibility study: 60. Randomised trial: at least 525.

**Total final enrolment**

4

**Key exclusion criteria**

1. ECOG performance score 4
2. Prognosis of  $\leq 2$  weeks
3. Participation in another local competing supportive or palliative care trial
4. Dementia, delirium or other lack of capacity or communication which renders the patient unable to participate in the trial
5. Any other psychological disorder which, in the view of the investigator, renders the patient unable to participate
6. Unable to communicate in English or with the use of an interpreter

**Date of first enrolment**

01/09/2015

**Date of final enrolment**

03/03/2016

**Locations**

**Countries of recruitment**

England

Scotland

United Kingdom

**Study participating centre**

**Sheffield Teaching Hospitals NHS Foundation Trust**

Weston Park Hospital

Sheffield

United Kingdom

S10 2JF

**Study participating centre**

**NHS Greater Glasgow and Clyde**

Stobhill Hospital

Glasgow

United Kingdom

G12 0XH

**Study participating centre**

**University Hospital Birmingham NHS Foundation Trust**

Queen Elizabeth Hospital

Birmingham

United Kingdom

B15 2TH

**Study participating centre**

**Sandwell and West Birmingham Hospitals NHS Trust**

City Hospital

Birmingham

United Kingdom

B18 7QH

## **Sponsor information**

**Organisation**

Sheffield Teaching Hospitals NHS Foundation Trust

**Sponsor details**

Royal Hallamshire Hospital

Glossop Road

Sheffield

England

United Kingdom

S10 2JF

**Sponsor type**

Hospital/treatment centre

**Website**

<http://sheffieldclinicalresearch.org>

**ROR**

<https://ror.org/018hjpz25>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

The Trial Management Group plan to publish an article regarding the difficulties encountered in setting up this complex trial, to be submitted for peer review and publication in 2017.

**Intention to publish date**

31/12/2017

**Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol (other)</a>		08/04/2016	12/04/2022	No	No
<a href="#">HRA research summary</a>			26/07/2023	No	No