

Physical activity level as an outcome measure for use in cancer cachexia trials: a feasibility study

Submission date 05/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/12/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/08/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Version 1.1

Study information

Scientific Title

Study objectives

Patients with lung or upper-gastrointestinal cancer will find the wearing of an activity monitor over one week acceptable. This has been defined as 80% of patients finding the device acceptable, demonstrated by them wearing the monitor 80% of the time.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Oxfordshire Research Ethics Committee A Study on the 8th March 2007 (ref: 07/Q1604/16).

Study design

Non-randomised, unblinded single-group design

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Palliative care in cancer patients

Interventions

Use of an ActivPAL free-living activity monitor (PAL technologies, Glasgow, UK) to assess free-living activity over one week. There is no control group in this trial, the activity monitors will be used for a period of one-week and, as we are assessing acceptability as a primary endpoint, there is no follow-up beyond this period.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Percentage acceptability of assessing physical activity level with an ActivPAL monitor over one week in patients with lung or upper gastro-intestinal cancer.

Secondary outcome measures

1. Correlation between the stepping component and the non-stepping component of the activity score
2. Limits of agreement between the measured stepping component of the activity score and an estimate of the stepping component based on step count; step count for each participant multiplied by the mean 'activity per step' calculated from all participants

All secondary endpoints will be assessed retrospectively, after one week, using the data uploaded from the activity monitors.

Overall study start date

01/08/2007

Completion date

01/05/2008

Eligibility**Key inclusion criteria**

1. Diagnosis of lung or upper-gastrointestinal cancer
2. Eastern Cooperative Oncology Group performance status of 0 - 2
3. Adequate understanding of verbal and written English

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

60

Key exclusion criteria

1. Currently receiving chemo-radiation therapy
2. Less than four weeks post surgery

Date of first enrolment

01/08/2007

Date of final enrolment

01/05/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Macmillan Reader in Palliative Medicine and Medical Oncology

Nottingham

United Kingdom

NG5 1PB

Sponsor information

Organisation

University of Nottingham (UK)

Sponsor details

Research Innovation Services

Kings Meadow Campus

Lenton Lane

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Sponsor type

University/education

Website

<http://www.nottingham.ac.uk/>

ROR

<https://ror.org/01ee9ar58>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (UK) (Ref: C18598/A8211)

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

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	01/12/2010		Yes	No