

The role of advanced brain magnetic resonance imaging techniques in small cell lung cancer

Submission date 22/06/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/07/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-using-advanced-type-MRI-scan-look-risk-factors-small-cell-lung-cancer-spread-club-01>

Contact information

Type(s)

Scientific

Contact name

Dr Susan Harden

Contact details

Oncology Centre, Box 193
Cambridge University Hospitals NHS Foundation Trust
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

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susan.harden@addenbrookes.nhs.uk

Additional identifiers

Protocol serial number

CLUB01 version 1.0 May 2009

Study information

Scientific Title

A non-randomised controlled single centre study to investigate the role of advanced brain magnetic resonance imaging techniques in small cell lung cancer

Acronym

CLUB01

Study objectives

We hypothesise that by developing ways to look for subtle changes in magnetic resonance imaging (MRI) images before the cancer deposits (metastases) themselves are big enough to be visualised by current methods, we may be able to predict which patients are most at risk for developing brain metastases.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire 1 Research Ethics Committee (REC), ref: 09/H0304/59, expected to be approved on 21/07/2009

Study design

Non-randomised controlled single-centre study

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Small cell lung cancer

Interventions

This is a single centre non-randomised observational imaging feasibility study. There will be a maximum of 4 MRI scans (interventions) over a 1 year period and the total duration recruitment will be 2 years, therefore a study duration of 3 years to complete the interventions with routine clinical follow-up to 5 years as standard.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Identification of the subset of SCLC patients at high risk for developing brain metastases, based on novel imaging at diagnosis, correlated retrospectively with clinical outcome.

Key secondary outcome(s)

Radiological disease progression:

1. Local incidence of asymptomatic brain metastases detected by conventional MRI at diagnosis
2. Local incidence of brain metastases detected after chemotherapy by conventional MRI

Completion date

09/11/2011

Eligibility

Key inclusion criteria

1. Ability to give written informed consent
2. Aged greater than 18 years, either sex
3. Histologically or cytologically confirmed small cell lung cancer
4. No previous malignancy
5. No prior chemotherapy
6. Satisfactory renal function (ethylenediaminetetraacetic acid [EDTA] clearance greater than 60 ml/min)
7. Satisfactory World Health Organization (WHO) performance status 0, 1 or 2

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

16

Key exclusion criteria

1. Prior chemotherapy or radiotherapy to primary tumour
2. Central nervous system (CNS) disease
3. Previous or coexistent malignancies
4. Pregnancy or breastfeeding
5. Any other medical condition making participation in a clinical trial undesirable

Date of first enrolment

01/09/2009

Date of final enrolment

09/11/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Cambridge University Hospitals NHS Foundation Trust

Cambridge

United Kingdom

CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK)

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results			27/07/2022	No	Yes