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

Submission date	Recruitment status	[ ] Prospectively registered
22/06/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/07/2022	Cancer	[ ] 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

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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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			27/07/2022	No	Yes