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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please contact CCTC at Addenbrooke's Hospital: +44 (0)1223 216083 to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/09/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 sequential patients

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
England

United Kingdom

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Trust R&D Dept, Box 277
Addenbrooke's Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/addenbrookes/addenbrookes_index.html

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, 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
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

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