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A clinico-pathologic study of Primary Mediastinal B-cell lymphoma

Submission date 31/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 31/03/2010	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 10/09/2019	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-to-understand-more-about-the-growth-and-treatment-of-a-rare-type-of-non-hodgkins-lymphoma

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2006-005794-22

ClinicalTrials.gov (NCT)
NCT00944567

Protocol serial number
4002

Study information

Scientific Title
A clinico-pathologic study of Primary Mediastinal B-cell lymphoma

Acronym
IELSG 26

Study objectives
Aim of the study is to evaluate prospectively the role of PET-scans in the management of primary mediastinal lymphoma treated with convential approaches.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 12/06/2007 (ref: 07/Q1704/68)

Study design
Non-randomised interventional multicentre process of care trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Lymphoma; Disease: Lymphoma (non-Hodgkin's)

Interventions
lymphoma, diffuse large B-cell lymphoma

Follow Up Length: 120 month(s)
Study Entry: Registration only

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Response rate on PET scanning following initial chemotherapy and at the end of all treatment

Key secondary outcome(s))
1. Progression Free Survival
2. Overall Survival

Completion date
31/05/2010

Eligibility

Key inclusion criteria
1. Primary mediastinal diffuse large B-cell lymphoma, CD20 positive. Patients must have histological confirmation of the diagnosis, and in addition have a dominant mass within the anterior mediastinum.
2. No prior treatment of lymphoma. Patients may have received corticosteroids for up to 1 week for the relief of local compressive symptoms.
3. Any stage of disease
4. Age at least 18 years
5. Fit to receive chemotherapy with curative intent
6. Able and willing to give informed consent, and to undergo staging including PET scanning
7. Willingness to comply with an appropriate contraceptive method in women of childbearing potential or men

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
125

Key exclusion criteria
1. Evidence of clinically significant cardiac disease, as defined by history of symptomatic ventricular arrhythmias, congestive heart failure or myocardial infarction within 12 months before study entry
2. Cardiac compromise due to local extension of lymphoma will not be an exclusion criterion in the absence of other cardiac disease
3. Impairment of bone marrow function (WBC < 3.0 x 10^9/L, ANC < 1.5 x 10^9/L, PLT < 100 x 10^9/L), unless due to involvement by lymphoma
4. Major impairment of renal function (serum creatinine > 2 x upper normal) or liver function (ASAT/ALAT > 2.5 x upper normal, total bilirubin > 2.5 x upper normal), unless due to lymphoma involvement
5. Known HIV infection. Patients will not be tested routinely.
6. Pregnant or lactating women
7. Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial

Date of first enrolment
16/01/2009

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton Clinical Trials Unit, MP131
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Research organisation

Funder Name
International Extranodal Lymphoma Study Group (IELSG) (Switzerland)

Results and Publications

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	10/06/2014	10/09/2019	Yes	No
Results article	results	20/08/2015	10/09/2019	Yes	No
Results article	results	12/07/2018	10/09/2019	Yes	No
Basic results			16/05/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes