ISRCTN88720356 https://doi.org/10.1186/ISRCTN88720356

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

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

**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

**ClinicalTrials.gov (NCT)**
NCT00944567

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

**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)

## Primary study design
Interventional

## Study design
Non-randomised interventional multicentre process of care trial

## 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 |