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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
31/03/2010		[_] Protocol		
Registration date	Overall study status	[] Statistical analysis plan		
31/03/2010	Completed	[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-growthand-treatment-of-a-rare-type-of-non-hodgkins-lymphoma

Contact information

Type(s) Scientific

Contact name Mrs Joanne Simon

Contact details University of Southampton Clinical Trials Unit, MP131 Tremona Road Southampton United Kingdom SO16 6YD

Additional identifiers

EudraCT/CTIS number 2006-005794-22

IRAS number

ClinicalTrials.gov number NCT00944567

Secondary identifying numbers 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

Secondary study design Non randomised study

Study setting(s) Hospital

Study type(s) Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Response rate on PET scanning following initial chemotherapy and at the end of all treatment

Secondary outcome measures

1. Progression Free Survival 2. Overall Survival

Overall study start date 16/01/2009

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

Age group

Adult

Lower age limit

18 Years

Sex Both

Target number of participants Planned Sample Size: 120; UK Sample Size: 120

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 England

United Kingdom

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

Sponsor information

Organisation Southampton University Hospitals NHS Trust (UK)

Sponsor details Tremona Road Southampton England United Kingdom SO16 6YD **Sponsor type** Hospital/treatment centre

Website http://www.suht.nhs.uk/home.aspx

ROR https://ror.org/0485axj58

Funder(s)

Funder type Research organisation

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

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Basic results	Details	Date created	Date added 16/05/2019	Peer reviewed? No	Patient-facing? No
<u>Results article</u>	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