ISRCTN51837425 https://doi.org/10.1186/ISRCTN51837425

An evaluation of therapy for B-cell lymphoma with Bortezomib

Submission date 30/03/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/03/2011	**Overall study status** Completed	
Last Edited 05/06/2025	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-bortezomib-with-rchop-for-dlbcl-remodl-b

Study website
http://www.ctu.soton.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2010-022422-32

IRAS number

ClinicalTrials.gov number

NCT01324596

Secondary identifying numbers
UKCRN ID: 9800

Study information

Scientific Title
A Randomised Evaluation of Molecular guided therapy for Diffuse large B-cell Lymphoma with Bortezomib

Acronym
REMoDLB

Study objectives
This study of treatment for diffuse large Bcell lymphoma aims to determine whether adding bortezomib to standard combination chemotherapy and rituximab (RCHOP) can improve progression free survival. Molecular studies have indicated the heterogenous biology of this disease identifying two subgroups (ABC and GCB) and this knowledge will be applied prospectively to determine whether a subgroup of patients might benefit more from the addition of bortezomib. Patients will be randomised to one of two groups (RBCHOP or RCHOP) on the basis of their molecular subgroup.

Ethics approval required
Old ethics approval format

Ethics approval(s)
10/H0405/79; First MREC approval date 24/01/2011

Study design
Randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Diffuse large B-cell lymphoma

Interventions
RB-CHOP, Rituximab, Cyclophsophamide, vincristine, Prednisolone, Doxorubicin, Bortezomib; R-CHOP, Rituximab, Cyclophosphamide, Doxorubicin, Prenisolone, Vincristine; Follow Up Length: 60 month(s); Study Entry : Single Randomisation only

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Bortezomib

Primary outcome measure
Progression-free survival; Timepoint(s): The primary endpoint is progression-free survival.

Secondary outcome measures
Disease-free survival; Timepoint(s): Disease-free survival will be measured from the time of documentation of disease-free state (CR or C; Event-free survival (time to treatment failure); Timepoint(s): Event-free survival (time to treatment failure) is measured from the day of registration to any trea; Overall survival; Timepoint(s): Overall survival will be measured from the day of registration to the date of death from any cause; Response duration; Timepoint(s): Response duration is defined as the time from documentation of response (ie,CR, CRu or PR) until the; Response Evaluation; Timepoint(s): Response will be assessed in accordance with the International Workshop Standardized Response Criter; Time to progression; Timepoint(s): Time to progression (TTP) is defined as the time from registration until documented lymphoma progres

Overall study start date
13/04/2011

Completion date
12/04/2020

Eligibility

Key inclusion criteria
1. Histologically confirmed Diffuse large B-cell lymphoma (DLBCL), expressing CD20
2. Sufficient diagnostic material should be available to forward to Haematological Malignancy Diagnostic Service (HDMS) for gene expression profiling and central pathology review
3. Core biopsies are acceptable, however the molecular profiling success rate is inferior compared to larger surgically acquired tissue samples
4. Best diagnostic practice encourages investigators to seek the latter approach whenever clinically appropriate
5. Not previously treated for lymphoma and fit enough to receive combination chemoimmunotherapy with curative intent
6. Age >18 years
7. Stage IAX (bulk defined as lymph node diameter >10cm) to stage IV disease and deemed to require a full course of chemotherapy

8. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
9. Adequate bone marrow function with platelets >100x109/L; neutrophils >1.0x109/L at study entry, unless lower figures are attributable to lymphoma
10. Serum creatinine <150µmol/L, measured or calculated creatinine clearance >30mls/min, serum bilirubin <35µmol/L and transaminases <2.5x upper limit of normal at the time of study entry, unless attributable to lymphoma
11. Cardiac function sufficient to tolerate 300mg/m2 of doxorubicin
12. A pre-treatment echocardiogram is not mandated, but recommended in patients considered at higher risk of anthracycline cardiotoxicity
13. No concurrent uncontrolled medical condition
14. Life expectancy >3 months
15. Adequate contraceptive precautions for all patients of child bearing potential
16. A negative serum pregnancy test for females of child bearing potential or those <2 years after the onset of the menopause
17. Patients will have provided written informed consent
18. Target gender: male and female
19. Lower age limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 940; UK Sample Size: 940; Description: 940 patients with DLBCL

Total final enrolment
1128

Key exclusion criteria
1. Previous history of treated or untreated indolent lymphoma, however newly diagnosed patients with DLBCL who are found to also have small cell infiltration of the bone marrow or other diagnostic material (discordant lymphoma) will be eligible.
2. Uncontrolled systemic infection
3. History of cardiac failure of uncontrolled angina
4. Clinical CNS involvement
5. Serological positivity for Hepatitis C, B or known HIV infection. Viral serological testing is not mandated for study entry, but considered standard of care. Patients who are HepBsAg positive will not be eligible.
6. Serious medical or psychiatric illness likely to affect participation or that may compromise the ability to give informed consent
7. Active malignancy other than fully excised squamous or basal cell carcinoma of the skin or carcinoma in situ of the uterine cervix in the preceding 5 years
8. History of allergic reaction to substances containing boron or mannitol

9. Patient unwilling to abstain from green tea and preparations made from green tea as bortezomib may interact with these
10. Any co-existing medical or psychological condition that would compromise ability to give informed consent

Date of first enrolment
13/04/2011

Date of final enrolment
12/04/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Southampton Clinical Trials Unit
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Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

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Sponsor type
University/education

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Industry

Funder Name
Janssen-Cilag Ltd

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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2019	24/04/2019	Yes	No