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A phase III multicentre randomised clinical trial comparing rituximab with cyclophosphamide, doxorubicin, vincristine and prednisone given every 14 days and rituximab with cyclophosphamide, doxorubicin, vincristine and prednisone given every 21 days for the treatment of patients with newly diagnosed diffuse large B cell non-Hodgkin's lymphoma

Submission date 05/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/10/2006	**Overall study status** Completed	
Last Edited 28/05/2013	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-treatment-every-2-weeks-or-every-3-weeks-for-non-hodgkins-lymphoma

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2.0

Study information

Scientific Title

Acronym
R-CHOP 14 vs 21

Study objectives
R-CHOP 14 vs 21 is a randomised multicentre phase III trial of chemotherapy in patients with untreated diffuse large B cell non-Hodgkin's lymphoma. Its aim is to investigate whether the efficacy of rituximab and cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP) chemotherapy given every 21 days for eight cycles can be improved by rituximab and CHOP given every 14 days for six cycles (two additional rituximab infusions will be given after the completion of CHOP).

As of 15/02/2011 the anticipated end date in this trial record has been updated from 01/02/2011 to 31/08/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Hull local research ethics committee on 18/05/2004 (ref: 04/Q1104/27)
2. The Royal Free Hospital & Medical School Research Ethics Committee approved the PET sub study ammendment on 17/09/2008 (added 23/02/10)

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diffuse Large B-Cell Lymphoma

Interventions
Arm A: R-CHOP 21: eight cycles of CHOP and eight cycles of rituximab, every 21 days
Arm B: R-CHOP 14: six cycles of CHOP and eight cycles of rituximab, every 14 days

Please note that this trial has been extended to include the PET sub study. The previous end date was 14/03/2008. As of 23/02/10 recruitment for the PET sub study is ongoing and recruitment for the main R-CHOP study has been completed (target reached Nov 2008).

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone

Primary outcome(s)
The primary endpoint of this study is overall survival.

Key secondary outcome(s))
The secondary endpoints are:
1. Failure free survival
2. Toxicity
3. Complete response rates

Completion date
31/08/2011

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Histologically proven Diffuse Large B Cell non-Hodgkin's Lymphoma (DLBCL) according to the current World Health Organisation (WHO) classification including all morphological variants. The B cell nature of the proliferation must be verified by the positivity with an anti-CD20 antibody. All histology will be reviewed by a central Lymphoma Trials Office pathology panel
3. No previous chemotherapy, radiotherapy or other investigational drug for this indication
4. Bulky stage IA (defined as lymph node or lymph node mass greater than 10 cm in diameter), stage II, stage III and IV
5. WHO performance status zero to two
6. Adequate bone marrow function with platelets more than 100 x 10^9/l, neutrophils more than 1.5 x 10^9/l at the time of study entry unless attributed to bone marrow infiltration by lymphoma
7. Serum creatinine less than 150mmol/l, serum bilirubin less than 35mmol/l and transaminases less than 2.5 upper limit of institutional normal range unless attributed to lymphoma
8. Normal MUltiple-Gated Acquisition (MUGA) scan or EchoCardioGram (ECG) without any areas of abnormal contractility. Patients must have an acceptable Left Ventricular Ejection Fraction (LVEF) = 50% (only applicable if aged over 70, known diabetic over 65, past history of cardiac disease or hypertension or abnormal resting ECG)
9. No concurrent uncontrolled medical condition
10. No active malignant disease other than basal or squamous cell carcinoma of the skin or carcinoma in situ of the uterine cervix in the last ten years
11. Life expectancy more than three months

12. Adequate contraceptive precautions for all patients of childbearing potential
13. Written, informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
1. T-cell lymphoma or transformed follicular lymphoma
2. Previous history of treated or non-treated indolent lymphoma. However, patients not previously diagnosed who have a diffuse large B-cell lymphoma with some small cell infiltration in bone marrow or lymph node may be included
3. Past history of heart failure or uncontrolled angina pectoris
4. Central nervous system, meningeal involvement or cord compression by the lymphoma
5. Cardiac contra-indication to doxorubicin (abnormal contractility on echocardiography or nuclear medicine examination [MUGA])
6. Neurological contra-indication to vincristine (e.g. pre-existing diabetic neuropathy)
7. Any other serious active disease
8. General status that does not allow the administration of eight courses of CHOP according to the investigator
9. Positive serology for Human Immunodeficiency Virus (HIV), Hepatitis B or Hepatitis C
10. Medical or psychiatric conditions that compromise the patients ability to give informed consent

Date of first enrolment
14/03/2005

Date of final enrolment
31/08/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Department of Oncology
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Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
Chugai Pharma Europe Ltd (ref JH/SP)

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	25/05/2013		Yes	No