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A parallel randomised phase II trial of cyclophosphamide, adriamycin, vincristine and prednisolone (CHOP) chemotherapy with or without Bortezomib in relapsed mantle cell lymphoma

Submission date 18/03/2008	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 16/05/2008	**Overall study status** Completed	
Last Edited 24/03/2022	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-chop-chemotherapy-with-or-without-bortezomib-for-relapsed-mantle-cell-lymphoma

Study website
http://www.mantlestudy.org

Contact information

Type(s)
Scientific

Contact name
Dr Simon Rule

Contact details
Department of Haematology
Level 07
Derriford Hospital
Plymouth
United Kingdom
PL6 8DH
+44 (0)1752 517505
none@example.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Ply-26s

Study information

Scientific Title
A parallel randomised phase II trial of cyclophosphamide, adriamycin, vincristine and prednisolone (CHOP) chemotherapy with or without Bortezomib in relapsed mantle cell lymphoma

Acronym
Bortezomib Study

Study objectives
The addition of bortezomib to cyclophosphamide, adriamycin, vincristine and prednisolone (CHOP) chemotherapy will improve the response rates and the duration of these responses in patients with relapsed mantle cell lymphoma (MCL), when compared to CHOP chemotherapy alone.

As of 17/02/2011 the anticipated end date for this trial has been updated from 28/02/2010 to 30 /04/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cornwall and Plymouth Research Ethics Committee on 23/02/2007 (ref: 07/Q2103/7)

Study design
Randomised open-label multicentre study, with a 1:1 randomisation between the two treatment groups

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
Relapsed or refractory mantle cell lymphoma

Interventions
There are two treatment groups in this study. Both use the CHOP chemotherapy regimen as described below. One group of patients will receive this regimen alone, and the other will receive the same dose and schedule, with the addition of bortezomib (Velcade®):

CHOP alone:
The following CHOP regimen will be given on a 21-day cycle for a maximum of eight cycles:
Day 1: Doxorubicin 50 mg/m^2 intravenous (IV)
Day 1: Cyclophosphamide 750 mg/m^2 IV
Day 1: Vincristine 1.4 mg/m^2 (maximum dose of 2 mg) IV
Days 1 - 5: Prednisolone 100 mg orally

CHOP and bortezomib (Velcade®):
The following CHOP and bortezomib regimen will be given on a 21 day cycle for a maximum of eight cycles:
Day 1: Bortezomib 1.6 mg/m^2 given as 3 - 5 second IV push
Day 1: Doxorubicin 50 mg/m^2 IV
Day 1: Cyclophosphamide 750 mg/m^2 IV
Day 1: Vincristine 1.4 mg/m^2 (maximum dose of 2 mg) IV
Days 1 - 5: Prednisolone 100 mg orally
Day 8: Bortezomib 1.6 mg/m^2 given as 3 - 5 second IV push

Patients will be followed up until death.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Cyclophosphamide, adriamycin, vincristine and prednisolone (CHOP), bortezomib (Velcade®)

Primary outcome measure
Response to the treatment(s) in terms of complete response, and partial response. As these outcomes will be measured until the patient relapses or progresses, the exact timepoints of the outcomes cannot be given precise times.

Secondary outcome measures
1. Duration of response to treatment
2. Time to progression
3. Overall survival rates
4. Toxicity

As these outcomes will be measured until the patient relapses or progresses, the exact timepoints of the outcomes cannot be given precise times.

Overall study start date
01/06/2007

Completion date
30/04/2011

Eligibility

Key inclusion criteria
1. Male and female subjects 18 years and older
2. A confirmed diagnosis of MCL including expression of cyclin D1 or evidence of t(11;14), such as by cytogenetics, fluorescent in situ hybridisation (FISH) or polymerase chain reaction (PCR)
3. Refractory to, or relapse, or progression following completion of first line anti-neoplastic therapy
4. All chemotherapy regimens are permissible and can be given in combination with rituximab
5. Prior splenectomy or localised radiotherapy is permissible
6. Measurable disease
7. Karnofsky Performance Status (KPS) greater than 50% (Eastern Cooperative Oncology Group [ECOG] grade 0 - 2)
8. Absolute neutrophil count greater than 1000 cells/mcg not related to lymphoma
9. Platelets greater than 30,000 cells/mcg
10. Aspartate transaminase less than 3 x upper limit of normal (ULN), alanine transaminase less than 3 x ULN, total bilirubin less than 2 x ULN, and calculated creatinine clearance greater than 20 mL/min
11. Toxic effects of previous therapy or surgery resolved to grade 2 or better
12. Female subject is either post-menopausal or surgically sterilised or willing to use an acceptable method of birth control
13. Male subject agrees to use an acceptable method for contraception for the duration of the study
14. Voluntary written informed consent before performance of any study-related procedure not part of normal medical care, with the understanding that consent may be withdrawn by the subject at any time without prejudice to future medical care

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90 patients

Key exclusion criteria
1. Known serological positivity for hepatitis B virus (HBV), hepatitis C virus (HCV) or human immunodeficiency virus (HIV)
2. Previous treatment with Velcade®
3. Anti-neoplastic therapy within three weeks before day 1 of cycle 1
4. Nitrosoureas within six weeks before day 1 of cycle 1
5. Rituximab, alemtuzumab (Campath®) or other unconjugated therapeutic antibody within four weeks before day 1 of cycle 1
6. Radiation therapy within three weeks before day 1 of cycle 1
7. Major surgery within two weeks before day 1 of cycle 1
8. History of allergic reaction attributable to compounds containing boron or mannitol
9. Diagnosed or treated for a malignancy other than MCL within five years before day 1 of cycle 1, with the exception of complete resection of basal cell carcinoma, squamous cell carcinoma of the skin, or any in situ malignancy
10. Active systemic infection requiring treatment
11. Female subject is pregnant or breast-feeding. Confirmation that the subject is not pregnant must be established by a negative serum beta-human chorionic gonadotropin (beta-hCG) pregnancy test result obtained during screening. Pregnancy testing is not required for post-menopausal or surgically sterilised women.
12. Serious medical or psychiatric illness likely to interfere with participation in this clinical study
13. Concurrent treatment with another investigational agent. Concurrent participation in non-treatment studies is allowed, if it does not interfere with participation in this study.

Date of first enrolment
01/06/2007

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Haematology
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Plymouth Hospitals NHS Trust (UK)

Sponsor details
Research and Development Office
Room N17
ITTC Building
Tamar Science Park
Derriford
Plymouth
England
United Kingdom
PL6 8BX

Sponsor type
Hospital/treatment centre

Website
http://www.plymouthhospitals.nhs.uk/Pages/Home.aspx

ROR
https://ror.org/05x3jck08

Funder(s)

Funder type
Industry

Funder Name
Johnson and Johnson Pharmaceuticals (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results			24/03/2022	No	Yes