Phase II study of Bortezomib, Adriamycin and Dexamethasone (PAD) therapy for previously untreated patients with multiple myeloma: Impact of minimal residual disease (MRD) in patients with deferred ASCT

Submission date	Recruitment status No longer recruiting	Prospectively registered		
22/02/2011		☐ Protocol		
Registration date 22/02/2011	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
19/05/2022	Cancer			

Plain English summary of protocol

http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-bortezomib-adriamycin-dexamethasone-as-first-treatment-for-myeloma-padimac

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number 2010-021598-35

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 8726

Study information

Scientific Title

Phase II study of Bortezomib, Adriamycin and Dexamethasone (PAD) therapy for previously untreated patients with multiple myeloma: Impact of minimal residual disease (MRD) in patients with deferred ASCT (PADIMAC)

Acronym

PADIMAC

Study objectives

The overall aim of the trial is to provide a reliable estimate of the 2-year progression-free survival (PFS) for patients who receive no further treatment after achieving a major response to induction therapy with PAD (Bortezomib, Adriamycin and Dexamethasone).

Background: Multiple myeloma (MM) is a cancer of white blood cells called plasma cells. The recent incorporation of new agents with significant activity against MM (such as bortezomib) into frontline regimens has resulted in high overall and complete response rates prior to ASCT (autologous stem cell transplant). The substantial activity seen with these new drug combinations prompts an urgent re-examination of the role and timing of ASCT in MM treatment, particularly as recent data indicate that patients who have already achieved a complete response (CR) following induction therapy obtain no further benefit from ASCT. Therefore, the aim of this phase II study is to provide a reliable estimate of the PFS of patients achieving major response post-induction who receive no further treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

10/H0502/58

Study design

Non-randomised interventional trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Haematological Oncology; Disease: Myeloma

Interventions

PAD, Patients will receive treatment to maximum response + 1 cycle, with a minimum of 4, and maximum of 6 cycles each of 21 days

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Bortezomib, adriamycin, dexamethasone

Primary outcome measure

2-year PFS for patients who, having achieved CR/VGPR following PAD therapy, do not receive any further treatment

Secondary outcome measures

Not provided at the time of registration

Overall study start date

01/11/2010

Completion date

01/04/2015

Eligibility

Key inclusion criteria

- 1. Previously untreated patients with symptomatic myelom
- 2. Patients suitable for high dose therapy and ASCT
- 3. = 18 years of age
- 4. Performance score (PS) of 0-3 (ECO.G). Measurable disease as defined by one of the following:
- 4.1. Secretory myeloma: Monoclonal protein in the serum or monoclonal light chain in the urine (Bence Jones protein ?200mg/24hours), or serum free light chain (SFLC, involved light chain ? 100mg/L provided the FLC ratio is abnormal)
- 4.2. Non-secretory myeloma: ? 30% plasma cells in the marrow (aspirate and/or biopsy) and at least one plasmacytoma ? 2 cm as determined by clinical examination or applicable radiographs (i. e., MRI or CT scan)

- 5. Adequate full blood count within 14 days before registration:
- 5.1. Platelet count =75x109/L
- 5.2. Absolute neutrophil count (ANC) = 1x109/L
- 6. Adequate renal function within 14 days before registration:
- 6.1. Creatinine clearance >30ml/min
- 7. Adequate hepatobiliary function within 14 days before registration:
- 7.1. Total bilirubi<2 x upper limit of normal (ULN)
- 7.2. ALT/AST < 2.5 x ULN
- 8. Adequate pulmonary function:
- 8.1. No evidence of a history of infiltrative pulmonary disease. If a history, then KCO/DLCO (Carbon Monoxide diffusion in the lung) =50% and/or no requirement for supplementary continuous O2
- 9. Adequate cardiac function:
- 9.1. Left ventricular ejection fraction (LVEF) =40% by echocardiogram and ECG.
- 10. If female and of childbearing potential (WCBP), must have a negative pregnancy test (either serum or urine HCG)
- 11. Able to give informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

Planned Sample Size: 120

Total final enrolment

153

Key exclusion criteria

- 1. Grade 2 peripheral neuropathy or neuropathic pain as defined by NCI Common Terminology Criteria for Adverse Events version 4.0 (CTCAE v4.0)
- 2. Pregnant or breast-feeding
- 3. Unwilling to use adequate contraception during the study and for 6 months after the end of the study treatment womnle of childbearing potential (WCBP) or male whose partner is WCBP
- 4. Known history of allergy contributable to compounds containing boron or mannitol
- 5. Any medical or psychiatric condition which, in the opinion of the investigator, contraindicates the patients participation in this study

Date of first enrolment

01/11/2010

Date of final enrolment

01/04/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Cancer Research UK & UCL Cancer Trials Centre, 90 Tottenham Court Road
London
United Kingdom
W1T 4TJ

Sponsor information

Organisation

University College London (UK)

Sponsor details

Institute of Child Health, Endocrinology London England United Kingdom WC1N 1EH

Sponsor type

University/education

Website

http://www.ucl.ac.uk/ich/homepage

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type

Research organisation

Funder Name

Leukaemia and Lymphoma Research (UK)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

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?
<u>Plain English results</u>			11/05/2022	No	Yes
Basic results		03/05/2021	19/05/2022	No	No
HRA research summary			28/06/2023	No	No