ISRCTN03381785 https://doi.org/10.1186/ISRCTN03381785

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
22/02/2011

Recruitment status
No longer recruiting

Registration date
22/02/2011

Overall study status
Completed

Last Edited
19/05/2022

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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

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Additional identifiers

Clinical Trials Information System (CTIS)
2010-021598-35

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
Not provided at the time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Cancer Research UK & UCL Cancer Trials Centre, 90 Tottenham Court Road
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Sponsor information

Organisation
University College London (UK)

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

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