Cardamon

Carfilzomib/Cyclophosphamide/Dexamethasone with maintenance carfilzomib in untreated transplant-eligible patients with symptomatic MM to evaluate the benefit of upfront ASCT

PBSCH, Post-PBSCH and Randomisation forms

Site	
Name of sender	
Contact email address	
Contact phone number	
Contact fax number	
Pharmacy contact	
Pharmacy email address	
Pharmacy fax number	
Date	D D M M Y Y Y Y

Please fax forms (9 pages in total) to
Cardamon Trial Coordinator
0207 679 9861

The forms will be checked for accuracy and eligibility and the trial arm allocation faxed/emailed back to the site & pharmacy contacts

General enquires: **020 7679 9860**
Randomisations: **020 7679 9860** between 9.00am and 5.00pm
Fax: **020 7679 9861**
E-mail: **ctc.cardamon@ucl.ac.uk**

CANCER RESEARCH UK

Cancer Research UK and UCL Cancer Trials Centre

UCL

Additional instructions for completing forms

The 'Peripheral Blood Stem Cell Harvest (PBSCH) Form' should be used to collect patient data on the patient's stem cell harvest and randomisation, if applicable.

The 'Post-Peripheral Blood Stem Cell Harvest (PBSCH) and Randomisation Form' should be used to collect patient data once they have completed their first 4 cycles of CarCyDex treatment and PBSCH. Assessments should be performed within 14 days after PBSCH.

Specific Fields

- Please ensure that you are using the correct units (i.e. haemoglobin in g/dL). If your local report uses different units please convert these before entering them on the form
- Please ensure you complete the drug details for both the original mobilisation and subsequent remobilisations if applicable
- Patients achieving a response of <PR will not proceed to randomisation and should be followed up in line with the protocol
- Disease responses must be confirmed by the local investigator
- Please ensure a progression/relapse form is submitted for patients with progressive disease

Completing forms

- Ensure all entries are clear, legible and written in black ink
- Avoid the use of abbreviations and acronyms
- **Do not leave any fields blank. In case of missing data**
    - ND (not done) if a test has not been performed or a measure not taken. If applicable state the reason
    - NA (not applicable) if a measure is not applicable
    - NK (not known) if data is unknown. This should only be used once every effort to obtain the data has been exhausted.
- The Principal Investigator (PI) is responsible for the accuracy of the data reported on the CRF
- Please ensure that all adverse events are recorded on the adverse event form and the form is attached
- CRFs may only be completed by an appropriately qualified individual delegated as responsible by the PI on the site delegation log
- CRF Footer section
    - The "completed by" Name should be clearly legible
    - Each CRF should be signed and dated by the person completing the form
    - Do not complete the *UCL CTC Use only* section
- **The CRF should be sent/faxed to the Cancer Trials Centre (CTC) with a copy retained at the Site** (ensure when photocopying the page that the copy is added to the CRF booklet in the same place where the original was stored)

If you have any questions about how to complete this form please contact the Cardamon Trial Coordinator on: 020 7679 9860

PBSCH Form

Stem cell mobilisation and harvest

Did the patient undergo stem cell mobilisation and harvest post-CarCyDex therapy?

1= Yes, please go to the next section
2= No, please complete below:

If **No**, please specify reason:
(choose <u>one</u> option only)

1 = Disease progression—Patient off protocol treatment—to be followed up as per protocol *(please complete first progression and treatment summary forms)*
2 = Patient withdrawal—Patient off protocol treatment—to be followed up as per protocol *(please complete treatment summary form)*
3 = Patient died *(please complete treatment summary and death forms)*
4 = Patient unfit, please specify below:
5 = Other, please specify below:

Patient off protocol treatment—to be followed up as per protocol (please complete a treatment summary form)

Mobilisation

Drug	Total dose given (mg)	Start date (DD/MM/YYYY)	End date (DD/MM/YYYY)
		/ /	/ /
		/ /	/ /
		/ /	/ /
		/ /	/ /

Date of first stem cell collection D D M M Y Y Y Y

Number of harvest days:

Number of stem cells collected • x10^6 CD34+ cells/kg

Did the patient undergo remobilisation?

1= Yes, please go to the next section (Remobilisation) on page 4
2= No, please go to Harvest outcome section of page 4

PBSCH Form

Re-Mobilisation

Drug	Dose given (mg)	Start date (DD/MM/YYYY)	End date (DD/MM/YYYY)
		/ /	/ /
		/ /	/ /
		/ /	/ /

Date of stem cell collection D D M M Y Y Y Y Number of harvest days: ☐

Number of stem cells collected ☐☐ • ☐☐ x10^6 CD34+ cells/kg

Harvest Outcome

Was the peripheral blood stem cell harvest successful? ☐

1= Yes, please complete below
2= No—*Patient off protocol treatment—to be followed up as per protocol (please complete a treatment summary form)*

End of successful harvest D D M M Y Y Y Y Number of harvest days: ☐

Total number of stem cells collected ☐☐ • ☐☐ x10^6 CD34+ cells/kg

Post-PBSCH and Randomisation form

Haematology

Date of Haematology: D D M M Y Y Y Y

Haemoglobin g/dL ☐☐.☐☐

Platelets x 10^9/L ☐☐☐☐

Neutrophils x10^9/L ☐☐.☐☐

WBC Count x10^9/L ☐☐.☐☐

Lymphocytes x 10^9/L ☐☐.☐☐

Biochemistry

Date of Biochemistry D D M M Y Y Y Y

Calcium (corrected) mmol/L ☐☐.☐☐

Potassium mmol/L ☐☐.☐☐

Sodium mmol/L ☐☐☐

Creatinine µmol/L ☐☐☐.☐

Creatinine Clearance ml/min ☐☐☐☐

Serum urate µmol/L ☐☐☐.☐

Urea (mmol/L) ☐☐.☐☐

Bilirubin µmol/L ☐☐☐

Albumin g/L ☐☐☐

Alkaline Phosphatase IU/L ☐☐☐☐

Alanine Transaminase (ALT) IU/L ***OR*** Aspartate Transaminase (AST) IU/L ☐☐☐

Note: Please confirm ND if only AST or ALT assessed.

Phosphate mmol/L ☐☐☐.☐

Adverse events

Did the patient experience any adverse events between their post-induction assessment until post-PBSCH? ☐

1 = Yes *(please ensure adverse event form is submitted)*
2 = No

Quality of Life Questionnaire

Has the Quality of Life (QoL) been completed? ☐

1 = Yes; *please send to the CTC as soon as possible*
3 = Not done; please provide reason in box below:

☐

UCL CTC Use only: Form received: _____ Date form entered: _____ Initials: _____

Post-PBSCH and Randomisation form

Bone marrow biopsies

Bone marrow aspirate Date of sample D D M M Y Y Y Y

☐ 1= Present, complete % of plasma cells: ☐☐☐ %
2= Present, not measured
3= Absent

Bone marrow trephine Date of sample D D M M Y Y Y Y

☐ 1= Present, complete % of plasma cells: ☐☐☐ %
2= Present, not measured
3= Absent

Bone marrow aspirate sample must be sent to HMDS, Leeds following the PBSCH

BM aspirate for MRD (2ml) sent to HMDS, Leeds? **Sent?** 1=Yes 2= No ☐ **Date sample sent to lab:** D D M M Y Y Y Y

If No, please specify a reason: ☐

Soft tissue plasmacytoma/Extramedullary lesions

Does the patient have any soft tissue plasmacytomas/ Extramedullary lesions? ☐ 1= Yes, complete date of test and a separate line for each site involved
2= No

If yes, date of test D D M M Y Y Y Y

			Long axis	**Short axis**
Site involved:	☐	Bidimensional measurements (cm):	☐ X	☐
Site involved:	☐	Bidimensional measurements (cm):	☐ X	☐
Site involved:	☐	Bidimensional measurements (cm):	☐ X	☐

Post-PBSCH and Randomisation form

Efficacy assessments

Date of test D D M M Y Y Y Y

Please complete this section for all myeloma patients:

Paraprotein expression *(choose one option only)*

1= Single paraprotein expressed
2= Light chain only
3= Biclonal
4= Non-secretory

Paraprotein type key: 1 = IgG, 2 = IgA, 3 = IgM, 4 = IgD

Specify paraprotein type:

Serum paraprotein

4= Present, please complete result
5= Too faint to quantify
6= Absent
7= Not Done

(g/L)

Specify paraprotein type: *(If biclonal)*

Serum paraprotein

4= Present, please complete result
5= Too faint to quantify
6= Absent
7= Not Done

(g/L)

Serum free light chain: Kappa (mg/L) • **OR** Tick if not done

Serum free light chain: Lambda (mg/L) • **OR** Tick if not done

Serum free light chain Kappa/Lambda ratio: •

Normal range of Kappa/Lambda FLC ratio: –

Urinary light chain measurement

1= Present, quantifiable
Please complete 24h BJP result (in g/24h):
2= Too faint to quantify (24h BJP only)
3= Absent
4= Not done
5= Present, not formally quantified
(if unable to perform 24h BJP)

• Light chain type *(please choose one only):*

1= Kappa
2= Lambda
3 = N/A

Immunofixation (only to confirm CR)

Immunofixation Serum

1= Positive
2= Negative
3= Not done

Date of test D D M M Y Y Y Y

Immunofixation Urine

1= Positive
2= Negative
3= Not done

Date of test D D M M Y Y Y Y

UCL CTC Use only: Form received: _____ Date form entered: _____ Initials: _____

Post-PBSCH and Randomisation form

Imaging *(If clinically indicated or for response assessment if persistent soft tissue plasmacytomas present)*

		Date of test	Lytic or focal lesions? 1= Yes 2= No
MRI	1= Evidence of myeloma 2= No evidence of myeloma 3= Not done	D D M M Y Y Y Y	
CT	1= Evidence of myeloma 2= No evidence of myeloma 3= Not done	D D M M Y Y Y Y	
PET	1= Evidence of myeloma 2= No evidence of myeloma 3= Not done	D D M M Y Y Y Y	
Skeletal survey	1= Evidence of myeloma 2= No evidence of myeloma 3= Not done	D D M M Y Y Y Y	
Other imaging	1= Evidence of myeloma 2= No evidence of myeloma 3= Not done	D D M M Y Y Y Y	

Specify type of other imaging

Has an increase in number or size of lytic bone lesions been seen on any radiograph? 1 = Yes 2 = No

Post-PBSCH and Randomisation form

Response post-PBSCH

This section must be completed and signed by the local principal investigator or delegated investigator

Date of response assessment: D D M M Y Y Y Y

Disease response post PBSCH
Choose one option only

- 1= sCR
- 2= CR
- 3= VGPR
- 4= PR

Patient should proceed to Randomisation

- 5= MR
- 6= SD

Patient off protocol treatment—to be followed up as per protocol (Please submit treatment summary form)

7= PD — *Patient off protocol treatment—to be followed up as per protocol (Please complete first progression and treatment summary form)*

Is this response confirmed? (1=yes, 2=no)
(refer to IMWG criteria/protocol appendix 3)

Date confirmed: D D M M Y Y Y Y

Investigator name (print):

Investigator signature:

Date signed: D D M M Y Y Y Y

Name of person completing form:

Signature of person completing form:

Date completed: D D M M Y Y Y Y

The site PI or delegated investigator must sign to confirm that information within the CRF is accurate

Investigator name:

Investigator signature:

Date completed: D D M M Y Y Y Y

Randomisation Details (CTC USE ONLY)

Patient eligible for randomisation? **Yes** **No**

Trial arm allocated? **Consolidation** **ASCT**

Randomised by

Date of randomisation: D D M M Y Y Y Y