Cardamon

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

Post-Consolidation Form

Patient Initials	☐☐☐
Trial Number	C A R – ☐☐☐

(This form has 7 pages including cover sheet)

Please send forms to:

Cardamon Trial Coordinator
CR UK & UCL Cancer Trials Centre
90 Tottenham Court Road
London W1T 4TJ

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**

Additional instructions for completing forms

The Post-Consolidation form collects details of the patient's response to consolidation treatment. Assessments are to be performed within 14 days of completing the last cycle of consolidation

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.
- If any efficacy tests have not been done because they are not clinically indication, please ensure that you complete the boxes with ND to confirm that the tests were not done. A discrepancy will be raised for those fields left completely blank.
- Disease response should be confirmed by a 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 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

Post-Consolidation 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 [ ][ ][ ]

Phosphate mmol/L [ ][ ][ ] • [ ]

Adverse events

Has patient returned their diary card? [ ]

1 = Yes
2 = No

Did the patient experience any adverse events between their last cycle of consolidation and their post-consolidation assessment? [ ]

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

Has the Quality of Life (QoL) been completed? [ ]

1=Yes; please ensure the form is attached
3=No, please provide reason if not done:

[ ]

Date of QoL completion: D D M M Y Y Y Y

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

Post-Consolidation 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
4= Not done

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
4= Not done

Bone marrow aspirate sample must be sent to HMDS, Leeds after 4 cycles of consolidation treatment
Bone marrow aspirate and peripheral blood samples must also be sent to the UCL Cancer Institute Myeloma Lab at this time point

	Sent? 1=Yes 2= No	Date sample sent to lab
BM aspirate for MRD (2ml) to HMDS, Leeds	☐	D D M M Y Y Y Y
BM aspirate for genomic analyses (8ml) to the UCL Cancer Institute Myeloma Lab	☐	D D M M Y Y Y Y
Peripheral blood sample for genomic analyses (8ml) to the UCL Cancer Institute Myeloma Lab	☐	D D M M Y Y Y Y

If No to any of the above, 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-Consolidation Form

PET-CT sub study: Post-Consolidation scan details

(please complete for patients participating in the PET-CT sub-study only)

Date of PET-CT: D D M M Y Y Y Y

Date images transferred to PET core lab: D D M M Y Y Y Y

Efficacy assessments

Date of test D D M M Y Y Y Y

Please complete this section for all myeloma patients:

Paraprotein expression *(choose <u>one</u> 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 <u>one</u> 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-Consolidation Form

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

NB: If patient is participating in PET-CT sub study please complete section at the end of this page

		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-Consolidation Form

Response post-consolidation

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

Patient's response to consolidation treatment: *(choose one option only)*

1= sCR
2= CR
3= VGPR
4= PR
5= MR
6= SD

Patient may proceed to maintenance treatment *(please ensure a treatment summary form is submitted)*

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

8= Unable to assess—
Specify reason:

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

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