# Cardamon

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

# End of Induction Form

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

**(This form has 6 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 End of Induction Form should be used to collect patient data once they have completed their first 4 cycles of CarCyDex treatment. The End of Induction Form should be completed within 14 days of the completion of the 4th cycle of CarCyDex Induction and prior to 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 that you have answered the regarding adverse events
  - ◊ If no adverse events occurred, then simply answer "no" and there is no need to attach an adverse event form
  - ◊ If an adverse event is still ongoing from the previous cycle **you must provide an adverse event** form and enter these AEs, using the original start date of the AE
- For tests which are only required if clinically indicated (e.g. 24hr BJP) please indicate if they were not done by completing the boxes with ND
- 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**

# End of Induction Form

## Haematology

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

Haemoglobin g/dL

WBC Count x$10^9$/L

Platelets x $10^9$/L

Lymphocytes x $10^9$/L

Neutrophils x$10^9$/L

## Biochemistry

Date of Biochemistry D D M M Y Y Y Y

Calcium (corrected) mmol/L

Bilirubin µmol/L

Potassium mmol/L

Albumin g/L

Sodium mmol/L

Alkaline Phosphatase IU/L

Creatinine µmol/L

Alanine Transaminase (ALT) IU/L

*Or*

Creatinine Clearance ml/min

Aspartate Transaminase (AST) IU/L

Serum urate µmol/L

Phosphate mmol/L

Urea (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 induction and their post-induction assessment?

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

## Soft tissue plasmacytoma/Extramedullary lesions *(if present at registration)*

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 |

# End of Induction 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

# End of Induction Form



## Imaging *(Only if clinically indicated, or if soft tissue plasmacytomas present at registration)*

| | | 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

## Cardiac function

Type of scan performed:

1= Echocardiogram
2= MUGA scan

ECHO / MUGA — 1= Normal 2= Abnormal, specify: — Date of test: D D M M Y Y Y Y

ECG — 1= Normal 2= Abnormal, specify: — Date of test: D D M M Y Y Y Y

# End of Induction Form



## Response post-induction

***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 induction treatment: *(choose one option only)* ☐

1= sCR
2= CR
3= VGPR
4= PR
*Patient should now proceed to peripheral blood stem cell harvest*

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