# Cardamon

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

# Follow Up form / Long Term Follow Up Form

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

**(This form has 3 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 Follow up/Long Term Follow up Form is used to follow up all patients registered to the trial (provided they have not withdrawn consent) and to monitor overall and progression free survival. See section 9.7 of the protocol for further details.

**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.
- 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)

**Follow Up / Long Term Follow Up Schedule** (see section 9.7 of the protocol)

- Patients who complete all trial treatment (induction, consolidation/ASCT and maintenance) or discontinue study treatment for any reason other than progression/inadequate response/ inadequate bone marrow harvest should be followed up 3 monthly for 12 months post last trial treatment. After 12 months, patients should enter long term follow-up—see section 9.9 of protocol for further details
- Patients who progress at any point during the study treatment, achieve <PR after induction treatment, or have an inadequate stem cell harvest should continue to be followed up for survival and subsequent treatment information **at 6 monthly intervals from the date of progression as per long-term follow-up**
- Patients on long term follow up should be seen according to routine clinical practice, though not less than every 6 months
- A progression/relapse form should be submitted as soon as possible in the case of a relapse, regardless of the time until the next follow up visit

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

# Follow Up / Long Term Follow Up Form



Date of Visit: D D M M Y Y Y Y

Follow up month: ___ Months post treatment / relapse (delete as applicable)

Since the patient's last follow up has the patient or patient's partner become pregnant? ___
1 = Yes *(please complete the pregnancy report form)*
2 = No

Has the patient developed a secondary malignancy since last visit? ___
1 = Yes
2 = No

If yes please give details:

Patient status: ___
1 = Alive without progression
2 = Alive with progression/relapse (*Please complete disease progression form for 1st or 2nd relapse)*
3 = Deceased (*Please complete death form)*
4= Alive, in second remission
5= Alive, in third or later remission

If progressed, enter date of progression: D D M M Y Y Y Y

Has the patient had any further myeloma treatment since last visit? ___
1 = Yes
2 = No

If yes, start date of further myeloma treatment? D D M M Y Y Y Y

Type of myeloma treatment: ___
1 = Chemotherapy
2 = Radiotherapy
4 = Biological therapy
5 = Combination therapy
6 = Other

Please specify the treatment regimen given:

Best response to further treatment given: *(choose one only)* ___
1= sCR
2= CR
3= VGPR
4= PR
5= MR
6= SD
7= PD
8= not yet known (*please complete at next follow-up visit)*

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: _____