

Cardamon

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

Treatment Summary Form

Patient Initials	<input type="text"/>	<input type="text"/>	<input type="text"/>			
Trial Number	<input type="text" value="C"/>	<input type="text" value="A"/>	<input type="text" value="R"/>	– <input type="text"/>	<input type="text"/>	<input type="text"/>

(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



Cancer Research UK and UCL Cancer Trials Centre



Additional instructions for completing forms

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The treatment summary form collects details of the patient's treatment up until the start of maintenance.

Specific fields:

- Total number of cycles should include all treatment cycles regardless of whether the cycle was completed—even if a patient completed only 1 day of a cycle, it is considered a cycle.

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 if not required
 - 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)

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

Cardamon

Trial Number **C A R** –

Patient Initials

Treatment Summary Form

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To be completed for all patients

Did patient receive full protocol treatment?

1= Yes, please complete this section only
2= No, please complete both sections

Date treatment stopped/completed:

D	D	M	M	Y	Y	Y	Y
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Total number of CarCyDex treatment received:
(Induction + Consolidation)

Did patient have a Melphalan conditioned ASCT?

1= Yes
2= No

Will the patient start maintenance Carfilzomib?

1= Yes
2= No

Specify a reason for discontinuation or not completing protocol treatment:

(This includes Induction, Consolidation, PBSCH and ASCT where applicable)

(choose one option only from below)

1 = Disease Progression / Relapse (Please complete a Progression/Relapse form)

2 = Death (Please complete a Death form)

3 = Toxicity , please specify:

(Please complete an AE/SAE form as appropriate)

4 = Lost to follow up (Please complete a Withdrawal/Lost to Follow up form)

5 =Intercurrent illness preventing further treatment, please specify:

6 = Inadequate harvest

7 =Other, please specify:

Name of person completing form:

Signature of person completing form:

Date completed:

D	D	M	M	Y	Y	Y	Y
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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
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