

ALLG Trial Number:	MM17
Trial Name:	
A multicentre single arm study of carfilzomib-thalidomide-dexamethasone (CarTD) for newly diagnosed transplant-eligible multiple myeloma (MM) patients refractory to initial bortezomib-based induction therapy	
Lay Summary:	
<p>Patients with newly diagnosed myeloma (NDMM) who are fit enough for autologous stem cell transplant (ASCT) are currently treated with bortezomib based induction for tumour reduction before moving to stem cell collection and ASCT. It has been shown that the depth of response to induction therapy is a powerful predictor of patient outcome with deeper responses being associated with longer survival. Therefore, this study proposes to switch therapy in those patients who demonstrate a suboptimal response to bortezomib based induction, to a potentially more effective regimen.</p> <p>Carfilzomib is a second generation proteasome inhibitor currently undergoing clinical evaluation in Australia. Additionally, the combination of proteasome inhibitors and immunomodulatory agents (e.g. thalidomide, lenalidomide) has been shown to be highly effective in the context of MM induction therapy. This study, MM17, therefore proposes to evaluate the efficacy and safety of a combination of Carfilzomib, Thalidomide and Dexamethasone (CarTD) in patients demonstrating a suboptimal response to bortezomib based induction for transplant eligible (TE) NDMM in the hope to produce a better response prior to transplant.</p> <p>Patients demonstrating a suboptimal response to bortezomib based induction will be registered to the study and undergo 4 or 6 cycles of CarTD before stem cell collection and ASCT. Consolidation with 2 more cycles of CarTD and then a further 10 months of TD maintenance will follow. The outcomes to be measured include the overall response rate, and the safety of CarTD. Secondary outcomes to be measured are depth of response and progression free survival and overall survival.</p>	
Participating Hospitals:	
1. Alfred / 2. Geelong (Barwon Health) / 3. Canberra / 4. Icon Cancer Care / 5. Royal Adelaide / 6. Royal North Shore / 7. St Vincent's Melbourne / 8. Townsville	
Target Accrual (International):	N/A
Target Accrual (ALLG):	50
Expected Final Accrual Date:	December 2017