

ALLG Trial Number:	AML21
Trial Name:	
A phase Ib/II clinical evaluation of Ponatinib in combination with 5-azacitidine in FLT3-ITD positive acute myeloid leukaemia (PonAZA)	
Lay Summary:	
<p>A common mutation called FLT3-ITD is found in approximately 25% of patients with acute myeloid leukaemia (AML), and this mutation is linked to a high chance of relapse after chemotherapy and a poor outcome for these patients. This study aims to look at combining a drug which inhibits FLT3-ITD called Ponatinib and combining it with another drug called Azacytidine, which has already been used with other FLT3 inhibitors.</p> <p>This study has two parts; Phase Ib which involves finding the best dose of Azacytidine to combine with Ponatinib in terms of patient tolerability and safety. Patients (greater than or equal to 18 years of age) will be examined over two dose schedules with 6 patients in each group. In Phase II of the study, patients will be randomly assigned to 2 groups; one group will receive Ponatinib alone, the other will receive Azacytidine and Ponatinib. This is to see which treatment works the best.</p>	
Participating Hospitals:	
1. Alfred / 2. Calvary Mater Newcastle / 3. Geelong (Barwon Health) / 4. Princess Alexandra / 5. Royal Brisbane and Women's / 6. Royal Melbourne / 7. Westmead	
Target Accrual (International):	n/a
Target Accrual (ALLG):	60
Expected Final Accrual Date:	June 2019