Haematology Clinical Trials

The Department of Haematology at Flinders Medical Centre has a Clinical Trials Unit for research into the diagnosis, monitoring, and treatment of haematological disorders. This includes both blood cancers (leukaemia, lymphoma, myeloma, myelodysplasia and myelproliferative neoplasms) and non-malignant disorders, such as thrombosis and idiopathic thrombocytopenic purpura (ITP).

Our clinical trials in malignant haematology include Pharma-sponsored studies and international collaborative group studies along with trials of the Australasian Leukaemia & Lymphoma Group, the major national collaborative group for blood cancers. We are currently running 10 trials of new drug treatments, and 2 quality of life studies that help us to understand the patient's pathway and point of view during treatment. New trials will be opening in the coming months, and will be featured in a future FCIC newsletter.

Clinical research gives our patients access to innovative treatment, and can also create opportunities for scientific research that use samples collected from patients during treatment.

If you would like further information regarding any of the studies currently available, you can contact the Haematology Clinical Trials Unit – Kayleen Charles on (08) 8204 5453 or kayleen.charles@health.sa.gov.au.

MALIGNANT HAEMATOLOGICAL STUDIES – FLINDERS MEDICAL CENTRE

OPEN FOR ACCRUAL

Study	Description	Status
Iron Overload	An epidemiological study to assess the prevalence of iron overload using MRI in patients with transfusional siderosis (CICL670AAU05) *TIMES (**T**ransfusional **I**ron overload assessed by **M**agnetic r**ES**onance imaging)*	Open for accrual
Hodgkin Lymphoma	A Randomized, Open-label, Phase 3 Trial of A+AVD Versus ABVD as Frontline Therapy in Patients With Advanced Classical Hodgkin Lymphoma	Open for accrual
Non-Hodgkin's Lymphoma	A randomised, open label, multi-centre, Phase III study to investigate the efficacy of bendamustine compared to treatment of physician's choice in the treatment of subjects with indolent Non-Hodgkin's Lymphoma (NHL) refractory to rituximab: Protocol: BDM3502	Open for Accrual
Peripheral T-cell Lymphoma	A Multi-center, Randomized, Phase 3 Study of Sequential Pralatrexate Versus Observation in Patients with Previously Undiagnosed Peripheral T-cell Lymphoma Who Have Achieved an Objective Response Following Initial Treatment with CHOP-based Chemotherapy	Open for accrual
Chronic Lymphocytic Leukaemia	A Randomized, Multicentre, Open-label, Phase 3 Study of the Bruton's Tyrosine Kinase Inhibitor PCI-32765 versus Chlorambucil in Patient 65 Years or Older with Treatment-naïve Chronic Lymphocytic Leukaemia or Small Lymphocytic Leukaemia	Open for accrual

CLOSED TO ACCRUAL

Study	Description	Status
Chronic Lymphocytic Leukaemia	An Australasian, phase II, multicentre, randomised, dose intensification study investigating oral fludarabine, oral cyclophosphamide and i.v. rituximab (poFCivR) tolerance in previously untreated elderly (≥ 65 years old) patients with chronic lymphocytic leukaemia (CLL)	Follow up
Chronic Lymphocytic Leukaemia	A Phase 3, Multicenter, Randomized, Open-Label, Parallel Group Study Of The Efficacy And Safety Of Lenalidomide (Revlimid®) Versus Chlorambucil As First-Line Therapy For Previously Untreated Elderly Patients With B-Cell Chronic Lymphocytic Leukemia.	Follow up
Chronic Myeloid Leukaemia	A Phase II Study In Adult Patients With Newly Diagnosed Chronic-Phase Chronic Myeloid Leukaemia Of Initial Intensified Imatinib Therapy And Sequential Dose Escalation Followed By Treatment With Nilotinib In Suboptimal Responders To Determine The Rate And Duration Of Major Molecular Response.	Follow up
Chronic Myeloid Leukaemia	Extending molecular responses with Nilotinib in newly diagnosed CLM patients in chronic phase.	Follow up
Multiple Myeloma	A Phase III Randomized, Open-Label, 3-Arm Study To Determine The Efficacy And Safety Of Lenalidomide (Revlimid®) Plus Low-Dose Dexamethasone When Given Until Progressive Disease Or For 18 Four-Week Cycles *Versus* The Combination Of Melphalan, Prednisone, And Thalidomide Given For 12 Six-Week Cycles In Patients With Previously Untreated Multiple Myeloma Who Are Either 65 Years Of Age Or Older Or Not Candidates For Stem Cell Transplantation	Follow up
Myelofibrosis	A Randomized, Double-blind, Placebo-controlled Study of the JAK Inhibitor INCB018424 Tablets Administered Orally to Subjects with Primary Myelofibrosis (PMF), Post-Polycythemia Vera- Myelofibrosis (PPV-MF) or Post-Essential Thrombocythemia-Myelofibrosis (PET-MF) Short Title COntrolled MyeloFibrosis Study with ORal JAK inhibitor Treatment:	Follow up
Myelodysplasia	A randomized phase II study comparing the efficacy of 5azacitidine alone vs combination therapy with Lenalidomide and 5aza in patients with higher risk myelodysplastic syndromes (MDS) and low marrow blast count AML	Follow up
Acute Myeloid Leukaemia	A phase III, randomized, controlled, double-blind, multicentre clinical study of the efficacy and safety of Voreloxin and Cytarabine vs Placebo and Cytarabine in patients with first relapsed or refractory AML	Follow up