

Haematology Clinical Trials Research Team

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Current number of patients enrolled in trials: 125
Number of current trials: 12
Number of trials closed to accrual but in Follow-up: 7

TITLES OF CURRENT TRIALS (Principal Investigator {PI} – Data Manager {DM})

ACUTE MYELOID LEUKAEMIA

ALLG AML M12 PI: Arno Enno DM: Tara Novak

A placebo-controlled, randomised Trial of the effects of palifermin on severe oral mucositis following intensive induction chemotherapy incorporating high dose cytosine and a randomised trial of Idarubicin dose Escalation in consolidation therapy in patients with Untreated Adult Acute Myeloid Leukaemia.

ALLG AML M13 PI: Sandra Deveridge DM: Michele Gambrell

High dose cytarabine and Fludrabine without anthracycline for patients with core Binding Factor Acute Myeloid Leukaemia.

ALLG APML 4 PI: Michael Seldon DM: Michele Gambrell

A Phase II trial in patients with previously untreated Acute Promyelocytic Leukaemia (APML) to evaluate the effects of: i) adding arsenic trioxide to ATRA and idarubicin for remission induction and ii) adding arsenic trioxide to ATRA as consolidation

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NON HODGKIN'S LYMPHOMA

NHL 14 - PI: Mark Walsh DM: Tara Novak

Watch and Wait – An inter group randomised trial of rituximab versus a watch and wait strategy in patients with advanced stage, asymptomatic, non-bulky follicular lymphoma.

ALLG NHL11 PI: Sandra Deveridge DM: Tara Novak

Hyper/CVAD – A phase II study of modified "Hyper-CVAD" frontline therapy for patients with poor prognosis diffuse large B-Cell and peripheral T-cell non-Hodgkin's lymphoma.

ALLG LYO3 PI: Arno Enno DM: Tara Novak

WM + SLVL International randomised Study of Chlorambucil (max 12 cycles) vs fludarabine (max 6 cycles)

CHRONIC MYELOID LEUKAEMIA

ALLG CML ALL1 PI: Arno Enno DM: Tara Novak

A Phase II Pilot /study of Glivec combined with Induction Chemotherapy in blast-Phase CML and Ph + ve Acute Lymphoblastic Leukaemia (Denovo and relapsed).

STI571 GLIVEC PI: Philip Rowlings DM: Michele Gambrill

A randomized open-label of 400 mg v 800 mg of Glivec in patients with newly diagnosed, previously untreated chronic myeloid leukaemia in chronic phase. (CML-CP).

OTHER STUDIES

BIOSTATE

PI: Michael Seldon DM: Michele Gambrill Haemophilia Nurse: Kay Sheridan

A safety and effectiveness study of Biostate in patients with von Willebrand disease (CSLCT-CIO-03-97)

ASPIRE PI: Michael Seldon DM: Michele Gambrill

Placebo versus low-dose ASPIrin in the Prevention of Recurrent Venous Thromboembolism (ASPIRE)

BNP Study PI: Michael Seldon DM: Tara Novak

BNP testing in patient's receiving initial anthracycline. Using plasma from collected biochem samples.

R-IE Study

Outpatient Ifosfamide, Etoposide plus Rituximab (R-IE) for salvage in patients > 60 years with relapsed or refractory CD20 positive diffuse large B-cell lymphoma who are not candidates for stem cell transplant.

AWAITING APPROVAL FROM ETHICS

BOMeR

Bortezomib and Dexamethasone as Treatment and Maintenance for Multiple Myeloma Relapse. An Australian Myeloma Forum Multi-Centre Phase II Trial This study was submitted to Ethics on 17th November, 2006.

RELAPSED CLL- BIOGEN STUDY

Randomised, open label, multicentre phase 2 study to evaluate the safety and efficacy of Lumiliximab in combination with Fludarabine, Cyclo, and Rituximab versus Fludarabine, Cyclo, and Rituximab alone in subjects with relapsed CLL.

PROPOSED STUDIES

MM18 (Celgene) Multicenter, single- arm, open label safety study of Lenalidomide plus dexamethasone in previously treated pt's with MM

Oral tabs for 21 days every 28 days with oral pulse dexa (40mg days 1-4, 9-12 & 17-20 for each 28 day cycle for cycles 1-4. In cycle 5 Dex reduced to 40mg daily for days 1-4 every 28days. Treatment continues until disease progression.

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CLOSED TO ACCRUAL

NON HODGKIN'S LYMPHOMA

LOW4 PI: Arno Enno DM: Michele Gambrell

MabThera for remission induction and maintenance of relapsed follicular NHL.

CHRONIC LYMPHOCYTIC LYMPHOMA

ALLG-CLL2 PI: Sandra Deveridge DM: Michele Gambrell

Australian Leukaemia Study Group (ALSF) International Study on Treatment of CLL.

CLL8 PI: Sandra Deveridge DM: Tara Novak

Randomised trial of chemotherapy agents Fludarabine and Cyclophosphamide +/-MabThera for patients with untreated CLL.

CHRONIC MYELOID LEUKAEMIA

ALLG CML6 – PI: Philip Rowlings DM: Michele Gambrell

A Phase II Study in adult patients with newly-diagnosed chronic myeloid leukaemia of, initial intensified glivec therapy and sequential combination therapy for non-responders.

MULTIPLE MYELOMA

ALLG MM6 – PI: Arno Enno DM: Tara Novak

This is a Phase III multi-centre open label randomised study of 224 patients of maintenance therapy, Prednisone and zometa +/- thalidomide for patients with MM following ASCT.

ACUTE PROMYELOCYTIC LEUKAEMIA

APML3 – PI: Arno Enno DM: Michele Gambrell

A phase II trial of ATRA and intensive Idarubicin followed by molecular monitoring in patients with acute promyelocytic leukaemia.

NON HODGKIN'S LYMPHOMA

MDS

Azacitidine + BSC vs BSC +/-Chemo - PI: Arno Enno DM: Tara Novak

Randomised Trial of Azacitidine plus Best Supportive Care Versus Best Supportive Care +/- Chemotherapy for Myelodysplastic Syndromes (MDS)

Recent Publications:

- Seebach JD, Stussi G, Passweg JR, Loberiza FR Jr, Gajewski JL, Keating A, Goerner M, Rowlings PA, Tiberghien P, Eifenbein GJ, Gale RP van Rood JJ, Reddy V, Gluckman E, Bolwell BJ, Klumpp TR, Horowitz MM, Ringden O, Barrett AJ; GVHD Working Committee of Center for International Blood and Marrow Transplant Research. ABO blood group barrier in allogeneic bone marrow transplantation revisited. *Biol Blood Marrow Transplant.* 2005 Dec;11(12):1006-13.
- Johnson W, Kerridge I, Milton C, Carr D, Enno A, Bray L, Booth A. Hospital in the home (HITH) care following autologous stem cell transplantation for lymphoma and multiple myeloma. *Aust J Adv Nurs.* 2006 Jun-Aug;23(4):34-9.
- Enjeti AK, Walsh M, Seldon M. Spontaneous major bleeding in acquired factor X deficiency secondary to AL-amyloidosis. *Haemophilia.* 2005;11(5):535-8.