

**Please note the protocols within this list are highly complex and local policies for prescribing and supportive care should be referred to. The list below is advisory and not to be used as a prescribing template.**

**ALL - TRIALS**

It is best practise for all patients to be treated on the appropriate NCRI national trial for ALL.

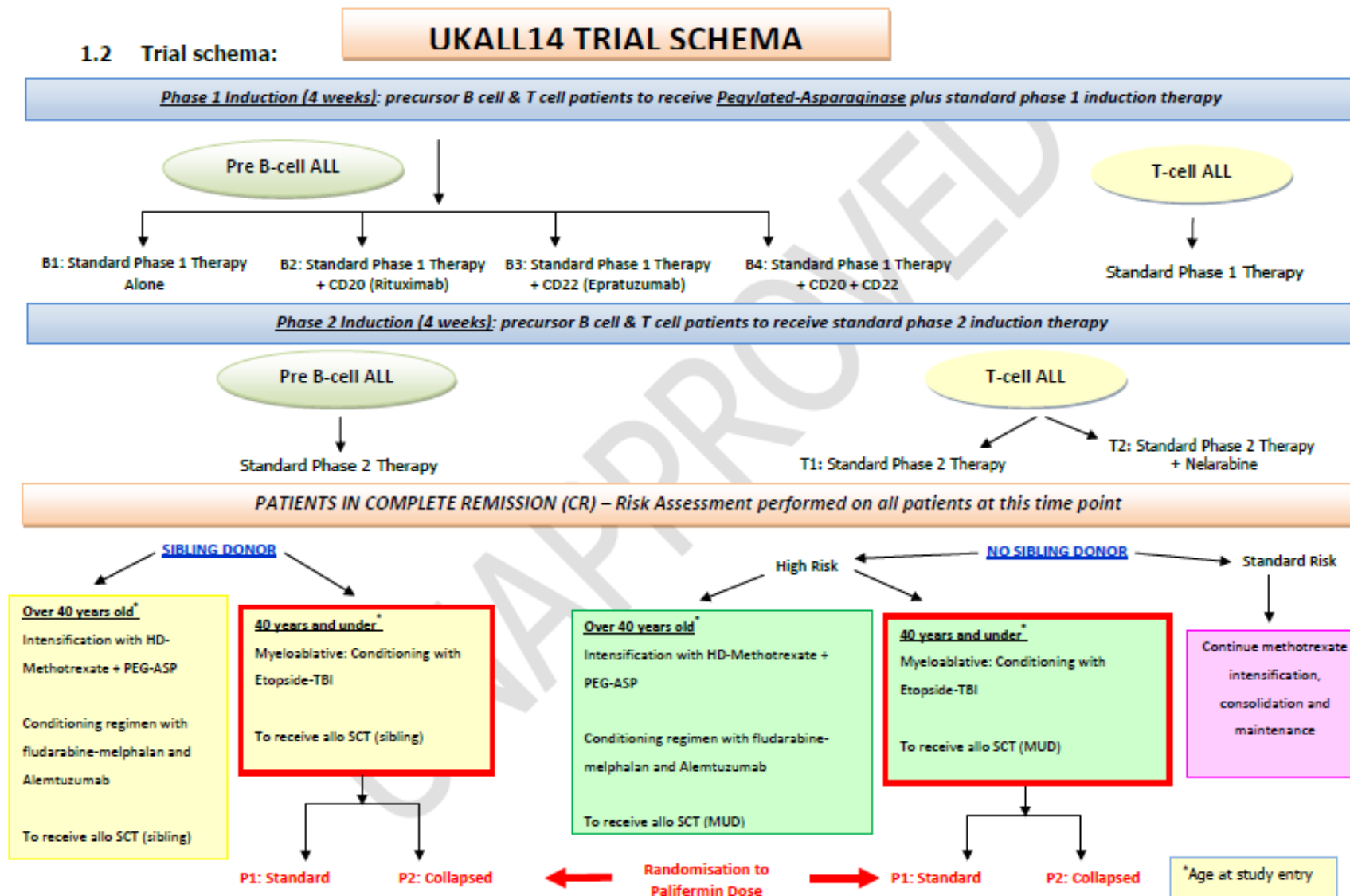
It is outside of the remit for this regimen list to provide a comprehensive detail of the regimens in these highly complex protocols – **PLEASE REFER TO the latest version of the national trial protocol for detailed protocols.**

**UKALL 2003** – for childhood and teenage/young adult (TYA) aged 16-25<sup>th</sup> birthday, with newly diagnosed acute lymphoblastic leukaemia.

This protocol is due to be replaced by the next trial UKALL2010: same age criteria will apply.

**UKALL 14** – for adults with newly diagnosed acute lymphoblastic leukaemia, age 25-60 YEARS. See trial schema below.

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<b>Acute Lymphoblastic Leukaemia – intensive treatment protocols (Adults)</b>		
<b>REGIMEN</b>	<b>Indication</b>	<b>Drugs</b>
UKALL2003 Regimen B	Young adults aged 16-24 (until 25 <sup>th</sup> birthday) with newly diagnosed ALL.  Note Down's syndrome appendix.	This is a highly complex, multi-phase protocol. Patients should not be treated with this protocol off study and should receive treatment in a trial centre and an age-appropriate environment (TYA services).  <b>It is imperative to refer to the trial protocol for detail and to ensure appropriate steps for MRD and randomisations are followed.</b>
UKALL 2003 Regimen C	Young adults aged 16-24 (until 25 <sup>th</sup> birthday) with newly diagnosed ALL.  Note Down's syndrome appendix.	This is a highly complex, multi-phase protocol. Patients should not be treated with this protocol off study and should receive treatment in a trial centre and an age-appropriate environment (TYA services).  It is imperative to refer to the trial protocol for detail and to ensure appropriate steps for MRD and randomisations are followed.
UKALL14 Trial regimen (trial to be launched and open May 2010)	Adults age 25-65 with newly diagnosed, previously untreated ALL.  Includes T-ALL, B-ALL and	This is a highly complex, multi-phase protocol. Patients should not be treated with this protocol off study and should receive treatment in a trial centre.  <b>It is imperative to refer to the trial protocol for detail and to ensure</b>

# Pan Birmingham Cancer Network: Haematology NSSG

Chemotherapy Regimens  
ALL intensive v1.0  
August 2010

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	Ph+ ALL. Excludes mature B-ALL (Burkitts)	<b>appropriate steps for MRD and randomisations are followed.</b>
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<b>Acute Lymphoblastic Leukaemia – intensive treatment protocols (Adults)</b>		
<b>REGIMEN</b>	<b>Indication</b>	<b>Drugs</b>
<p>UKALL12 Phase 1 induction</p> <p>Includes T-ALL, B-ALL and Ph+ ALL. Excludes mature B-ALL (Burkitts)</p>	<p>Adults age 25-65 with newly diagnosed, previously untreated ALL.</p> <p>Patients suitable for intensive therapy but not entering a trial as above.</p> <p>Induction therapy 1</p>	<p><b>NEVER GIVE INTRATHECAL AND INTRAVENOUS CHEMOTHERAPY ON THE SAME DAY.</b></p> <p>Daunorubicin 60 mg/m<sup>2</sup> i.v. by slow i.v. infusion on days 1,8,15 and 22. Vincristine 1.4 mg/m<sup>2</sup> (maximum 2 mg) by i.v. push days 1,8,15 and 22. Prednisolone 60 mg/m<sup>2</sup> p.o. days 1-28 then taper Allopurinol 300 mg daily p.o. L-asparaginase 10,000 units total dose i.m. daily days 17-28 inclusive. A test dose of 1000 IU intradermally should be administered before treatment commences.</p> <p><b>Methotrexate 12.5 mg intrathecally</b> day 24 only</p>
<p>UKALL 12 Phase 2 induction</p>	<p>Adults age 25-65 with newly diagnosed, previously untreated ALL.</p> <p>Patients suitable for intensive therapy but not entering a trial as above.</p> <p>Induction therapy 2</p>	<p>Phase II begins after phase 1 when white count is greater than 3.0 x 10<sup>9</sup>/L in patients with delayed haematological recovery.</p> <p>Cyclophosphamide 650 mg/m<sup>2</sup> i.v. days 1,15 and 29 of Phase II. Cytosine arabinoside 75 mg/m<sup>2</sup> i.v. days 1-4 inclusive, 8-11 inclusive, 15-18 inclusive and 22-25 inclusive. 6-mercaptopurine (MP) 60 mg/m<sup>2</sup> p.o. daily on days 1-28 inclusive of Phase II.</p> <p><b>INTRATHECAL METHOTREXATE IS NEVER GIVEN ON THE SAME DAY AS INTRAVENOUS CHEMOTHERAPY</b></p> <p><b>Methotrexate 12.5 mg intrathecally on days -1 , 7,14 and 21 of Phase II</b></p>

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Acute Lymphoblastic Leukaemia – intensive treatment protocols (Adults)		
REGIMEN	Indication	Drugs
UKALL12 Intensification  Includes T-ALL, B-ALL and Ph+ ALL. Excludes mature B-ALL (Burkitts)	Adults age 25-65 with newly diagnosed, previously untreated ALL.  Patients suitable for intensive therapy but not entering a trial as above.  Post induction therapy for patients achieving remission.	The intensification module begins two weeks after completion of Phase II induction, it should be postponed until WCC>3.0 x 10 <sup>9</sup> /L and platelets >100 x 10 <sup>9</sup> /L in those with delayed haematological recovery. <b>Refer to local Trust guidelines on the administration of high-dose methotrexate and folinic acid rescue.</b> Methotrexate 3 g/m <sup>2</sup> i.v. days 1,8 and 22 of the intensification course L-asparaginase 10,000 units i.m. on days 2, 9 and 23 of the intensification course. Leucovorin rescue 15 mg/m <sup>2</sup> i.v. in 50 ml of 5% Dextrose, 36 hours after the beginning of the methotrexate infusion and then for at least 72 hours depending on the methotrexate level (as per local Trust protocols).
UKALL 12 Consolidation (cycles 1-2)	Adults age 25-65 with newly diagnosed, previously untreated ALL.  Patients suitable for intensive therapy but not entering a trial as above.  Post intensification therapy – for patients not	Consolidation <b>Cycle 1</b> will begin when WCC> 3.0 x10 <sup>9</sup> /l and platelets > 100 x 10 <sup>9</sup> /L and neutrophils > 1.0 x 10 <sup>9</sup> /L Vincristine 1.4 mg/m <sup>2</sup> (maximum 2 mg) i.v. days 1, 8, 15 & 22 only. Cytosine arabinoside 75 mg/m <sup>2</sup> i.v. days 1-5 inclusive. Etoposide (VP16) 100 mg/m <sup>2</sup> i.v. days 1-5 inclusive. Dexamethasone 10 mg/m <sup>2</sup> p.o. days 1-28 inclusive.  <b>Cycle 2</b> will begin when WCC> 3.0 x10 <sup>9</sup> /l and platelets > 100 x 10 <sup>9</sup> /L

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	proceeding to allogeneic transplant	Cytosine arabinoside 75 mg/m <sup>2</sup> i.v. Etoposide (VP16) 100 mg/m <sup>2</sup> i.v.	days 1-5 inclusive. days 1-5 inclusive.
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Acute Lymphoblastic Leukaemia – intensive treatment protocols (Adults)		
REGIMEN	Indication	Drugs
UKALL 12 Consolidation (cycles 3-4)	Adults age 25-65 with newly diagnosed, previously untreated ALL.  Patients suitable for intensive therapy but not entering a trial as above.  Post intensification therapy – for patients not proceeding to allogeneic transplant	Consolidation <b>Cycle 3</b> begins when white count is >3.0 x 10 <sup>9</sup> /L and platelets >100 x 10 <sup>9</sup> /L. Daunorubicin 25 mg/m <sup>2</sup> days 1,8,15 and 22. Cyclophosphamide 650 mg/m <sup>2</sup> i.v. day 29 only. Cytosine arabinoside 75 mg/m <sup>2</sup> i.v. days 31-34 inclusive and 38-41. 6-thioguanine (TG) 60 mg/m <sup>2</sup> daily p.o. days 29-42  <b>Cycle 4</b> when the white count is >3.0 x 10 <sup>9</sup> /L and platelets >100 x10 <sup>9</sup> /L, and is identical with cycle 2, i.e. Cytosine arabinoside 75 mg/m <sup>2</sup> i.v. days 1-5 inclusive. Etoposide (VP16) 100 mg/m <sup>2</sup> i.v. days 1-5 inclusive.
UKALL12 Maintenance	Adults age 25-65 with newly diagnosed, previously untreated ALL.  Patients suitable for intensive therapy but not	Maintenance Mercaptopurine 75 mg/m <sup>2</sup> p.o. daily. Oral Methotrexate 20 mg/m <sup>2</sup> p.o. once a week  Vincristine 1.4 mg/m <sup>2</sup> (maximum 2 mg) i.v. every 3 months Prednisolone (EC or not) 60 mg/m <sup>2</sup> for 5 days p.o. every 3 months with Vincristine.

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	entering a trial as above.  Post consolidation therapy – for patients not proceeding to allogeneic transplant	Cytosine arabinoside 50 mg <b>intrathecally</b> (IT) every 3 months for 1 year <b>GIVE TWO WEEKS AFTER IV VINCRISTINE, NEVER ON THE SAME DAY.</b>  Septrin (co-trimoxazole) prophylaxis p.o. (960 mg) b.d. 3 days per week <b>The maintenance chemotherapy should continue for 18 months from the point of initiation of the consolidation therapy, i.e. for 18 months from week 20.</b>
<b>Acute Lymphoblastic Leukaemia – intensive treatment protocols (Adults)</b>		
<b>REGIMEN</b>	<b>Indication</b>	<b>Drugs</b>
Imatinib	Adults with Ph+ ALL.	Imatinib 400mg po once daily for 28 days.  Dose may be escalated to 600mg once daily, if tolerated.  Repeat cycle every 28 days until disease progression
High dose AraC+ Amsacrine	Relapsed/refractory ALL  For patients eligible for intensive therapy, who have relapsed or failed to achieve CR after 2 cycles of induction.	<b>Amsacrine</b> 200mg/m <sup>2</sup> iv Days 1-3 inclusive <b>Cytosine Arabinoside</b> 3gm/m <sup>2</sup> iv Days 1-5 inclusive