

Acute lymphoblastic leukaemia (ALL) trial XII (joint trial with Eastern Co-operative Oncology Group - E2993)

Submission date 25/10/2000	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 25/10/2000	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/10/2009	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00002514

Clinical Trials Information System (CTIS)
2005-006181-31

Protocol serial number
G8223452, MREC/02/2/84

Study information

Scientific Title

Acronym

UKALLXII

Study objectives

1. To compare effects of marrow ablative therapy using VP16 and total body irradiation followed by autologous bone marrow rescue (ABMT or Peripheral Stem Cell Rescue) with conventional consolidation and maintenance chemotherapy in adult patients between 15 and 55 years who have no HLA compatible donor
2. To examine (in a non-randomised study) differences in outcome in adult ALL in those patients who have an HLA compatible donor, who will be allocated allogeneic BMT versus those with a donor randomised to autologous BMT or conventional chemotherapy
3. To compare the outcome of the above three treatments or matched unrelated donor BMT in patients with Philadelphia chromosome positive disease and to examine the efficacy of additional Interferon during maintenance chemotherapy or after BMT

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Leukaemia

Interventions

1. Marrow ablative therapy using VP16 and total body irradiation followed by autologous bone marrow rescue (ABMT or Peripheral Stem Cell Rescue)
2. Conventional consolidation and maintenance chemotherapy

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Length of survival
2. Relapse rates

Key secondary outcome(s)

No secondary outcome measures

Completion date

30/09/2008

Eligibility

Key inclusion criteria

1. Adult patients between 15 and 55 years with previously untreated ALL
2. Morphological proof of ALL
3. Diagnosis has been made from bone marrow morphology with greater than 25% lymphoblasts by the French-American-British (FAB) criteria

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Prior malignancy for which chemotherapy or radiotherapy have been given
2. AML, MDS or other antecedent haematological disorder or lymphoid transformation of chronic myeloid leukaemia
3. Previously treated
4. Intercurrent life threatening disease
5. Pregnant or lactating

Date of first enrolment

01/01/1993

Date of final enrolment

30/09/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
University College Hospital
London
United Kingdom
WC1E 6AU

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/07/2006		Yes	No
Results article	results	01/03/2007		Yes	No
Results article	results on prospective outcome data	07/05/2009		Yes	No
Results article	results on clinical and biological features of participants	10/12/2009		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes