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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof A Goldstone

Contact details

University College Hospital Gower Street London United Kingdom WC1E 6AU

Additional identifiers

Clinical Trials Information System (CTIS)

2005-006181-31

ClinicalTrials.gov (NCT)

NCT00002514

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

Study design

Randomised controlled trial

Primary study design

Interventional

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, 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	i	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
<u>Study</u> <u>website</u>	Study website	11/11/2025	11/11 /2025	No	Yes