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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2000	**Overall study status** Completed	
Last Edited 21/10/2009	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ctsu.ox.ac.uk/projects/leuk/ukallxii/new-4th-dec-2006/ukallxii-protocol-version-5-0.pdf

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2005-006181-31

IRAS number

ClinicalTrials.gov number

NCT00002514

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
1. Length of survival
2. Relapse rates

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/1993

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

Age group
Adult

Sex
Both

Target number of participants
550

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
England

United Kingdom

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

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
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W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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