Medical Research Council Adult Acute Lymphoblastic Leukaemia Trial UKALL XA

Submission date 19/08/2002	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 19/08/2002	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 07/06/2012	Condition category Cancer	Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Dr - -

Contact details UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers MRC UKALL XA

Study information

Scientific Title

Study objectives Not provided at time of registration.

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) Not specified

Study type(s) Not Specified

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Leukaemia (acute)

Interventions

All patients receive induction, central nervous system (CNS) prophylaxis and maintenance. Patients are randomised to one of four treatment arms:

1. Arm A: Early intensification therapy to be given immediately after induction and before CNS prophylaxis.

2. Arm B: Late intensification therapy to be given following cranial radiotherapy at week 20 of maintenance.

3. Arm C: Intensification therapy to be given both immediately after induction and following cranial radiotherapy at week 20 of maintenance.

4. Arm D: No intensification therapy.

INDUCTION: Chemotherapy with vincristine, prednisolone, asparaginase, daunorubicin and intrathecal methotrexate.

INTENSIFICATION: Intensification therapy with vincristine, prendisolone, daunorubicin, thioguanine, etoposide, cytosine arabinoside and intrathecal methotrexate.

CNS PROPHYLAXIS: Cranial radiotherapy, intrathecal methotrexate plus mercaptopurine. MAINTENANCE: Maintenance therapy consisting of daily mercaptopurine, weekly methotrexate, monthly vincristine plus prednisolone. Treatment to be given for total of two years following complete remission.

Intervention Type Other

Phase Not Specified

Primary outcome measure Not provided at time of registration.

Secondary outcome measures Not provided at time of registration.

Overall study start date 01/01/1985

Completion date 31/12/1992

Eligibility

Key inclusion criteria 1. Newly diagnosed ALL 2. Aged >25 years

Participant type(s) Patient

Age group Adult

Sex Not Specified

Target number of participants Added as of 29/06/2007: 618

Key exclusion criteria Not provided at time of registration.

Date of first enrolment 01/01/1985

Date of final enrolment 31/12/1992

Locations

Countries of recruitment England

United Kingdom

Study participating centre UKCCCR Register Co-ordinator London United Kingdom NW1 2DA

Sponsor information

Organisation Medical Research Council (MRC) (UK)

Sponsor details 20 Park Crescent London United Kingdom 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	01/10/1997		Yes	No