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An International Collaborative Trial for Relapsed and Refractory Acute Lymphoblastic Leukaemia

Submission date 01/10/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/10/2003	**Overall study status** Completed	
Last Edited 04/03/2019	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-treatment-for-children-and-young-people-with-acute-lymphoblastic-leukaemia

Contact information

Type(s)
Scientific

Contact name
Prof Vaskar Saha

Contact details
Academic Unit of Paediatric & Adolescent Oncology
University of Manchester
Wilmslow Road
Manchester
United Kingdom
M20 4BX
+44 (0)161 446 3023
vaskar.saha@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number
2004-000052-16

IRAS number

ClinicalTrials.gov number

NCT00967057

Secondary identifying numbers
N/A

Study information

Scientific Title
An International Collaborative Trial for Relapsed and Refractory Acute Lymphoblastic Leukaemia

Acronym
ALLR3

Study objectives
To examine the biology of relapsed Acute Lymphoblastic Leukaemia (ALL) and improve its outcome using a combination of chemotherapy and nationally standardised approach to Haematopoietic Stem Cell Transplantation (HSCT).

Please note that as of 13/05/10 this record has been extensively updated. Ireland, Australia, New Zealand and the Netherlands have been added to the countries of recuitment. The end date of this trial has also been extended from 01/01/2010 to 31/12/2011. All other updates can be found in the relevant field with the above update date.

Please note that the primary contact has moved insitution, therefore as of 13/05/10 the contact and sponsor details have been updated. The previous sponsor and contact details are as follows.
Previous sponsor:
Barts and the London NHS Trust (UK)
Research and Development Department
3rd Floor Rutland House
42-46 New Road
Whitechapel
London
E1 2AX
United Kingdom
http://www.bartsandthelondon.org.uk

Previous contact address:
Dept of Paediatric Oncology and Haematology
1st Floor Eva Luckes House
Royal London Hospital
London
E1 1BB
United Kingdom

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Multicentre Research Ethics Committee for Wales (ref: 02/9 /21)

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
Relapsed and Refractory Acute Lymphoblastic Leukaemia (ALL)

Interventions
No additional procedures are required in the trial. The trial drugs have already been used in previous paediatric oncology trials for many years.

Randomisation closed December 2007

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Added 13/05/2010:
1. Evaluate Progression Free Survival (PFS) by risk group
2. Evaluate whether a minimal residual disease level (MRD) level of 10-4 is a suitable criteria at the end of induction on which to decide whether chemotherapy or stem cell transplantation (SCT) will be most beneficial to patients in the intermediate risk group.

Secondary outcome measures
Added 13/05/2010:
1. MRD as a surrogate marker for PFS
2. Randomised comparison between Mitoxantrone and Idarubicin

Overall study start date
06/01/2003

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. All children aged 1 - 18 years who have been previously diagnosed to have acute lymphoblastic leukaemia and have either relapsed after treatment or have primary refractory disease
2. For children who have relapsed, only those in whom this is the first relapse are eligible
3. Provide signed, written informed consent from parent and/or guardian
4. Protocol to have received national local ethical committee approval

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
480

Key exclusion criteria
1. Children less than 1 year old and young adults of 18 years of age and older
2. Children in whom this is not the first relapse of their disease
3. Children with first relapse who have already received chemotherapy or radiotherapy prior to starting R3
4. Children with mature B cell ALL

Date of first enrolment
06/01/2003

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Australia

England

Ireland

Netherlands

New Zealand

United Kingdom

Study participating centre
University of Manchester
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
Central Manchester University Hospitals NHS Foundation Trust (UK)

Sponsor details
Trust HQ
Corbett House
Manchester Royal Infirmary
Oxford Road
Manchester
England
United Kingdom
M13 9WL

Sponsor type
Hospital/treatment centre

Website
http://www.cmft.nhs.uk

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Charity

Funder Name

Cancer Research UK (UK) (ref: ONPG1A1R) - Funding for trial manager

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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	11/12/2010		Yes	No
Results article	results	03/10/2014		Yes	No
Results article	results	01/04/2019		Yes	No