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International protocol for the treatment of childhood anaplastic large cell lymphoma (ALCL)

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 19/10/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00006455

Secondary identifying numbers
NHL 2000/06

Study information

Scientific Title
International protocol for the treatment of childhood anaplastic large cell lymphoma (ALCL)

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)
Hospital

Study type(s)
Treatment

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
Lymphoma (non-Hodgkin's)

Interventions
Four arms:
Arm one: MTX (1 g/m2) over 24 hours with intrathecal
Arm two: MTX (1 g/m2) over 24 hours with intrathecal and Vinblastine for one year
Arm three: MTX (3 g/m2) over three hours without intrathecal
Arm four: MTX (3 g/m2) over three hours without intrathecal and Vinblastine for one year

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
MTX, vinblastine

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2000

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. ALCL diagnosed by local pathologist
2. Slides available for national review
3. Aged <22 years
4. No previous treatment
5. Appropriate ethical approval

Participant type(s)
Patient

Age group
Child

Upper age limit
22 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
Not applicable

Date of first enrolment
01/04/2000

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
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WC2A 3PX
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kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name

Cancer Research UK

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

Funder Name
United Kingdom Children's Cancer Study Group (UKCCSG)

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?
Plain English results				No	Yes
Results article	results	01/09/2010		Yes	No
Results article	results	26/05/2011		Yes	No
Results article	results	01/07/2011		Yes	No