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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 London United Kingdom WC2A 3PX +44 (0)207 317 5186 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, Cancer Research UK (CRUK), 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

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