

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

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|--------------------------|-----------------------------|--|
| Submission date | Recruitment status | <input type="checkbox"/> Prospectively registered |
| 01/07/2001 | No longer recruiting | <input type="checkbox"/> Protocol |
| Registration date | Overall study status | <input type="checkbox"/> Statistical analysis plan |
| 01/07/2001 | Completed | <input checked="" type="checkbox"/> Results |
| Last Edited | Condition category | <input type="checkbox"/> 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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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00006455

Protocol serial number

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

22 years

Sex

All

Key exclusion criteria

Not applicable

Date of first enrolment

01/04/2000

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Cambridge University Hospitals NHS Foundation Trust

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Cancer Research UK (CRUK) (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/09/2010 | | Yes | No |

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|--|-------------------------------|------------|------------|-----|
| <u>Results article</u> | results | 26/05/2011 | Yes | No |
| <u>Results article</u> | results | 01/07/2011 | Yes | No |
| <u>Participant information sheet</u> | Participant information sheet | 11/11/2025 | 11/11/2025 | No |
| <u>Plain English results</u> | | | No | Yes |