A randomised study comparing weekly alternating chemotherapy with three-weekly chemotherapy in advanced high grade non-Hodgkins lymphoma

Submission date	Recruitment status	Prospectively registered
01/07/2001	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
01/07/2001	Completed	Results
Last Edited	Condition category	Individual participant data
23/02/2015	Cancer	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

- - -

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

Study information

Scientific Title

A randomised study comparing weekly alternating chemotherapy with three-weekly chemotherapy in advanced high grade non-Hodgkins lymphoma

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

1. Regimen CAPOMET: Combination chemotherapy with CAPOMET (cyclophosphamide, adriamycin, prednisolone, vincristine, methotrexate and etoposide). A weekly regimen repeated every 4 weeks with the more myelotoxic combinations cyclophosphamide and adriamycin, methotrexate and etoposide alternating with the more marrow sparing combination prednisolone and vincristine, but ending with cyclophosphamide and adriamycin. Chemotherapy should be continued until complete remission plus 8 weeks with a minimum of 12 weeks of treatment.

2. Regimen CHOP-Methotrexate: Three weekly cycle of combination chemotherapy, CHOP-methotrexate (cyclophosphamide, adriamycin, prednisolone, vincristine and methotrexate) repeated until complete remission plus three cycles for a minimum of five cycles.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

CAPOMET (cyclophosphamide, adriamycin, prednisolone, vincristine, methotrexate and etoposide), CHOP-methotrexate (cyclophosphamide, adriamycin, prednisolone, vincristine and methotrexate)

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2000

Completion date

31/12/2000

Eligibility

Key inclusion criteria

- 1. High grade pathology, malignant lymphoma classified as: Centroblastic; Lymphoblastic; Immunoblastic; True histocytic; High grade unclassified
- 2. Advanced (stage III or IV, extensive abdominal or otherwise bulky stage II disease)
- 3. No specific age limit but considered able to tolerate either treatment regimen
- 4. No previous radiotherapy, chemotherapy or immunotherapy
- 5. No previous malignancy, except adequately treated basal cell carcinoma or in-situ carcinoma of cervix
- 6. No serious medical or psychological condition precluding adequate treatment
- 7. Able to tolerate daily fluid intake of at least 2 litres
- 8. Ability of participating clinician to support patients with severe marrow hypoplasia

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2000

Date of final enrolment

31/12/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre MRC Clinical Trials Unit

London United Kingdom NW1 2DA

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, 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