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

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 01/07/2001	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 23/02/2015	**Condition category** Cancer	[_] Individual participant data [_] 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NH3001

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