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A study to investigate the benefit of adjuvant chemotherapy following resection of localised intermediate grade gastro-intestinal lymphoma and to assess the effect of depth of penetration of the tumour on survival

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 21/11/2019	**Condition category** 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

Protocol serial number
LY04

Study information

Scientific Title
A study to investigate the benefit of adjuvant chemotherapy following resection of localised intermediate grade gastro-intestinal lymphoma and to assess the effect of depth of penetration of the tumour on survival

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lymphoma (non-Hodgkin's)

Interventions
Following complete local excision patients are randomised to one of two treatment arms depending on the stage of disease:

STAGE T1-2 N0 M0 PATIENTS:
1. Group A: No further treatment.
2. Group B: Chemotherapy with, cyclophosphamide, hydroxydaunorubicin, vincristine and prednisolone (CHOP) repeated every 21 days for three cycles.

STAGE T3-4 N0-2 M0 PATIENTS:
1. Group C: Chemotherapy with CHOP repeated every 21 days for three cycles.
2. Group D: Chemotherapy with CHOP repeated every 21 days for six cycles.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
16/10/1996

Eligibility

Key inclusion criteria
1. Intermediate and high grade gastrointestinal lymphoma excluding lymphoblastic and Burkitt's lymphoma. All histology will be reviewed by a panel and classified into mucosa-associated lymphoid tissue (MALT) and NON-MALT tumours
2. Complete surgical resection
3. Age 16 years or over
4. No previous chemotherapy or radiotherapy
5. No other previous or concomitant malignant disease except basal cell carcinoma or in situ carcinoma of the cervix
6. No other serious condition contraindicating chemotherapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1995

Date of final enrolment
16/10/1996

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary