

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/11/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1995

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

Age group

Adult

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1995

Date of final enrolment

16/10/1996

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