ISRCTN43154562 https://doi.org/10.1186/ISRCTN43154562

Protocol for a randomised trial of triple anti-Heliocobacter therapy versus chlorambucil in an endoscopically diagnosed low grade gastric lymphoma

Submission date
01/07/2001

Recruitment status
No longer recruiting

Registration date
01/07/2001

Overall study status
Completed

Last Edited
04/01/2012

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

Protocol serial number
LY03

Study information

Scientific Title

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)

Health condition(s) or problem(s) studied
Lymphoma (non-Hodgkins) cancer

Interventions
1. Regimen A: Colloidal bismuth 120 mg four times daily, metronidazole, 400 mg three times daily plus tetracycline 500 mg four times daily or amoxycillin 500 mg four times daily. In addition patients receive chlorambucil daily for 14 days, cycle to be repeated every 28 days for six cycles.

2. Regimen B: Colloidal bismuth 120 mg four times daily, metronidazole, 400 mg three times daily plus tetracycline 500 mg four times daily or amoxycillin 500 mg four times daily. No chlorambucil.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Cancer drug

Primary outcome(s)
Not provided at time of registration

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

Completion date
18/05/2001

Eligibility

Key inclusion criteria
1. Non-resected, partially or completely resected low grade gastric lymphoma
2. Age 16 or over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1996

Date of final enrolment
18/05/2001

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2009		Yes	No