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

Submission date	Recruitment status No longer recruiting Overall study status	Prospectively registered		
01/07/2001		☐ Protocol		
Registration date		Statistical analysis plan		
01/07/2001	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
04/01/2012	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

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