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

Registration date
01/07/2001

Last Edited
04/01/2012

Recruitment status
No longer recruiting

Overall study status
Completed

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
Dr - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1996

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

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
01/01/1996

Date of final enrolment
18/05/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
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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

Study outputs

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