

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

<b>Submission date</b> 01/07/2001	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/07/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/01/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# 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  
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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/02/2009		Yes	No