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Chlorambucil versus chlorambucil plus rituximab versus rituximab alone in malt lymphoma

Submission date 18/06/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 18/06/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 19/10/2018	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-chlorambucil-alone-rituximab-alone-or-chlorambucil-and-rituximab-together-for-malt-lymphoma

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1294

Study information

Scientific Title

Multi-centre randomised trial of chlorambucil versus chlorambucil plus rituximab versus rituximab alone in extranodal marginal zone b-cell lymphoma of mucosa associated lymphoid tissue (malt lymphoma)

Acronym
IELSG19/MALT Trial

Study objectives
The aim of the study is to assess the therapeutic activity and the safety of the combination of chlorambucil and rituximab in mucosa associated lymphoid tissue (MALT) lymphomas and to determine whether the addition of ritxuiamb to chlorambucil will improve the outcome of MALT lymphoma in comparison to treatment with chlorambucil alone. Also to compare the anti-tumor activity and safety of rituximab alone versus chlorambucil alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Multi-Centre Research Ethics Committee, 30/04/2003 (ref: 03/1/031). Amendment approved on the 30/10/2006.

Primary study design
Interventional

Study design
Multicentre randomised interventional treatment trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Lymphoma; Disease: Lymphoma (non-Hodgkin's)

Interventions
ARM A: Chlorambucil 6 mg/m2 daily orally (p.o.) for 42 consecutive days (weeks 1 - 6)
ARM B: Chlorambucil 6 mg/m2 daily p.o. for 42 consecutive days (weeks 1 - 6) and rituximab 375 mg/m2 intravenous (iv) on days 1, 8, 15, 22 during the first month (4 weekly doses)
ARM C: Rituximab 375 mg/m2 iv on days 1, 8, 15, 22 during the first month (4 weekly doses)

Study entry: single randomisation only

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Chlorambucil, rituximab

Primary outcome(s)
Event-free-survival (EFS) (failure or death from any cause) for all patients

Key secondary outcome(s)
1. Complete and partial remission rates for all patients
2. Response duration (time to relapse or progression) for responder patients
3. Progression-free-survival (PFS) (disease progression or death from lymphoma: for all patients
4. Overall survival for all patients
5. Acute and long-term toxicity

Completion date
30/06/2010

Eligibility

Key inclusion criteria
To be eligible for inclusion in this trial, patients must fulfill all the following criteria:
1. Histologically proven diagnosis of CD20-positive marginal zone B-cell lymphoma of MALT type arisen at any extranodal site
2. Any stage (Ann Arbor I - IV)
3. Either de novo, or relapsed disease following local therapy (including surgery, radiotherapy and antibiotics for H. pylori-positive gastric lymphoma)
4. No evidence of histologic transformation to a high grade lymphoma
5. Measurable or evaluable disease
6. Aged greater than 18 years
7. Life expectancy of at least 1 year
8. Eastern Cooperative Oncology Group (ECOG) performance status 0 - 2
9. No prior diagnosis of neoplasm within 5 years, except cervical intraepithelial neoplasia type 1 (CIN1) or localised non-melanomatous skin cancer
10. No prior chemotherapy
11. No prior immunotherapy with any anti-CD20 monoclonal antibody
12. No prior radiotherapy in the last 6 weeks
13. No corticosteroids during the last 28 days, unless prednisone chronically administered at a dose less than 20 mg/day for indications other than lymphoma or lymphoma-related symptoms
14. No evidence of clinically significant cardiac disease, as defined by history of symptomatic ventricular arrhytmias, congestive heart failure or myocardial infarction within 12 months before study entry
15. No evidence of symptomatic central nervous system (CNS) disease
16. No impairment of bone marrow function (white blood cells [WBC] greater than 3.0 x 10^9/L, absolute neutrophil count [ANC] greater than 1.5 x 10^9/L, platelets [PLT] greater than 100 x 10^9/L), unless due to lymphoma involvement
17. No major impairment of renal function (serum creatinine less than 1.5 x upper normal) or liver function (aspartate aminotransferase [ASAT]/alanine aminotransferase [ALAT] less than 2.5 upper normal, total bilirubin less than 2.5 x upper normal), unless due to lymphoma involvement
18. No evidence of active opportunistic infections
19. No known human immunodeficiency virus (HIV) infection
20. No active hepatitis B virus (HBV) and/or hepatitis C virus (HCV) infection
21. No pregnant or lactating status
22. Appropriate contraceptive method in women of childbearing potential or men
23. Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should

be discussed with the patient before registration in the trial
24. Informed consent must be given according to national/local regulations before randomisation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/08/2003

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MP131, University of Southampton Clinical Trials Unit
Southampton
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Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Research organisation

Funder Name
International Extranodal Lymphoma Study Group (UK)

Results and Publications

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?
Plain English results				No	Yes