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Chimeric anti-CD20 monoclonal antibody (Mabthera) in remission induction and maintenance treatment of relapsed follicular non-Hodgkin's lymphoma (NHL): a phase III randomised clinical trial (Intergroup Collaborative Study)

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 22/10/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EORTC 20981

Study information

Scientific Title
Chimeric anti-CD20 monoclonal antibody (Mabthera) in remission induction and maintenance treatment of relapsed follicular non-Hodgkin's lymphoma (NHL): a phase III randomised clinical trial (Intergroup Collaborative Study)

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-Hodgkin's)

Interventions
Arm 1: CHOP will be given at 3-week intervals. After three cycles patients will be evaluated for response. Patients with stable or progressive disease will go off study. A total of six cycles will be given.

Arm 2: CHOP plus Mabthera. Mabthera (iv) given on first day of each cycle of CHOP. Stable or progressive patients after three cycles will go off the study. A total of six cycles will be given.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
11/11/1998

Completion date
11/11/2005

Eligibility

Key inclusion criteria
1. Patients with Ann Arbour stages III or IV follicular NHL (at initial diagnosis) who have relapsed after a minimum of two adequate non-anthracycline containing systemic chemotherapy regimens. Patients pre-treated with other chemotherapy regimens are not eligible for this trial.
2. Patients should have achieved remission on at least one of the prior regimens (i.e. either on the first or second regimen)
3. Remission duration upon one of the prior regimens should have been at least 3 months
4. Previous treatment should have been at least 4 month of single agent therapy (e.g. chlorambucil) and/or at least four consecutive cycles of polychemotherapy (e.g. CVP) or purine analogues. Patients treated with chemotherapy not fulfilling these criteria are not eligible.
5. Follicular NHL according to the Revised European/American Lymphoma (REAL) classification, i. e. follicle centre lymphoma, follicular (provisional cytological grades I [small cell], II [mixed small cell and large cell], III [large cell])
6. Must be CD20 positive lymphoma
7. At least one mass should be present measurable by two perpendicular diameters by either physical or radiological examination
8. Aged 18 years or above
9. World Health Organization (WHO) performance status 0, 1 or 2
10. Patient information and written informed consent according to the rules of the respective country

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
465

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
11/11/1998

Date of final enrolment
11/11/2005

Locations

Countries of recruitment
Australia

Belgium

Canada

Denmark

Egypt

England

France

Hungary

Italy

Netherlands

New Zealand

Norway

Poland

Slovakia

Slovenia

South Africa

Sweden

Switzerland

United Kingdom

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

Sponsor information

Organisation
European Organisation for Research and Treatment of Cancer (EORTC) (Belgium)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.eortc.be

ROR
https://ror.org/034wxcc35

Funder(s)

Funder type
Research organisation

Funder Name
European Organisation for Research and Treatment of Cancer (EORTC) (Belgium)

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?
Plain English results				No	Yes
Results article	results	01/05/2010		Yes	No