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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)

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| **Submission date**<br>19/08/2002 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>19/08/2002 | **Overall study status**<br>Completed | |
| **Last Edited**<br>22/10/2018 | **Condition category**<br>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
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NW1 2DA

# Sponsor information

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

**Sponsor details**
83, Avenue E. Mounier
Bte 11
Brussels
Belgium
B-1200
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eortc@eortc.be

**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 |