

# Standard chemotherapy combination (Cyclophosphamide, Hydroxydaunorubicin, Vincristine, Prednisolone [CHOP]) with 1, 3 or 6 cycles of the monoclonal anti-CD20-antibody. Rituximab in first line therapy of follicular non-Hodgkins lymphoma.

<b>Submission date</b> 12/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/07/2014	<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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

**Scientific Title**

**Acronym**

HD2000

**Study objectives**

Six infusions of Rituximab, added to 6 cycles of standard chemotherapy (CHOP), are more effective than 1 or 3 infusions of Rituximab in the production of a molecular remission, as determined by t(14;18) real time Polymerase Chain Reaction (PCR) in peripheral blood and bone marrow.

**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)**

Treatment

**Participant information sheet**

**Health condition(s) or problem(s) studied**

Follicular Lymphoma World Health Organisation (WHO) Grade I and II, Stage 3-4

**Interventions**

6 x CHOP + 1 x Rituximab versus

6 x CHOP + 3 x Rituximab versus

6 x CHOP + 6 x Rituximab

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

CHOP and Rituximab

**Primary outcome measure**

Molecular remission rate after the end of six cycles of CHOP with various cycles of Rituximab antibodies, determined by t(14;18) real time PCR in peripheral blood and bone marrow.

**Secondary outcome measures**

1. Clinical remission rate
2. Duration of molecular and clinical response
3. Toxicity

**Overall study start date**

01/09/2000

**Completion date**

31/03/2006

**Eligibility****Key inclusion criteria**

1. Patients with histologically proven CD20+ follicular lymphoma (follicular lymphoma grade I, II), stage III and IV
2. Age >18 years, no upper limit
3. No pre-treatment except irradiation and/or corticosteroids
4. Requirement of therapy: one or more of the following: B-symptoms, hematopoietic insufficiency (leukopenia <1.5/nl, anemia hb <10 g/dl, platelets <100/nl)
5. Objective tumor progression (>50% increase in sum of tumor diameters in six months); 'bulky disease' (mediastinal/abdominal tumor >7.5 cm and/or other lymphnodes >5 cm)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

**Key exclusion criteria**

1. Age <18 years
2. Stage I or II
3. CD20 negativity
4. Karnofsky Index <80% or Eastern Cooperative Oncology Group (ECOG) >2
5. Pre-treatment with murine antibodies, severe organ impairment (heart, lung, neck) according to common criteria
6. Pre-treatment with any chemotherapy

**Date of first enrolment**

01/09/2000

**Date of final enrolment**

31/03/2006

**Locations****Countries of recruitment**

Germany

**Study participating centre**

Im Neuenheimer Feld 410

Heidelberg

Germany

69120

**Sponsor information****Organisation**

University of Heidelberg (Germany)

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.klinikum.uni-heidelberg.de/index.php?id=725>

**ROR**

<https://ror.org/038t36y30>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Sponsored and funded by Roche and University of Heidelberg

## 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	01/10/2012		Yes	No