ISRCTN47525145 https://doi.org/10.1186/ISRCTN47525145

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.

Submission date 12/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/01/2006	**Overall study status** Completed	
Last Edited 24/07/2014	**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

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

Primary study design
Interventional

Study design
Randomised Controlled Trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
Industry

Funder Name
Sponsored and funded by Roche and University of Heidelberg

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?
Results article	results	01/10/2012		Yes	No