

Randomized Phase III trial: Maintenance therapy with the monoclonal chimeric antibody rituximab compared to observation in patients with CD20+ B-cell Non-Hodgkins lymphoma

Submission date 13/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 08/12/2005	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 27/11/2015	Condition category Cancer	☐ 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

Protocol serial number

HD2002 Rituximab maintenance

Study information

Scientific Title

Randomized Phase III trial: Maintenance therapy with the monoclonal chimeric antibody rituximab compared to observation in patients with CD20+ B-cell Non-Hodgkins lymphoma

Acronym

HD2002 Rituximab maintenance

Study objectives

The objective of this trial is to examine whether event free survival, overall survival and cure rate of patients with CD20+ B-cell Non-Hodgkins lymphoma can be improved by a maintenance therapy of 8 cycles rituximab q 3 months (total 24 months). The hypothesis is that residual tumor cells can be destroyed in vivo by the rituximab maintenance therapy.

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

B-cell lymphoma

Interventions

Rituximab maintenance compared to observation

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Rituximab

Primary outcome(s)

Event-free survival

Key secondary outcome(s)

Overall survival, progression-free survival

Completion date

31/12/2006

Eligibility

Key inclusion criteria

1. B-cell CD20+ Non-Hodgkins Lymphoma (primary therapy and relapse). At study entry patients with aggressive lymphoma need to have a complete remission, if a residual tumor is still present a positron-emission-tomography examination needs to reveal no active tumor. Patients with indolent lymphoma need at least a partial remission to enter this trial
2. Age above 18 years
3. Karnofsky Index above 60
4. Contraception and negative pregnancy test of women in reproductive age
5. Valid patient approval

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Manifest cardiac insufficiency
2. Chronic obstructive lung disease with hypoximia
3. Uncontrolled hypertension
4. Renal insufficiency (creatinine above 2 mg/dl)
5. Hepatic insufficiency (Bilirubin above 2.0 mg/dl)
6. Pregnancy
7. Breast feeding
8. Severe psychiatric illness
9. Human immunodeficiency virus (HIV) positive patients
10. Primary cerebral lymphoma
11. Previous allogeneic transplant

Date of first enrolment

24/06/2002

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Germany

Study participating centre

INF 410

Heidelberg

Germany

69120

Sponsor information

Organisation

University of Heidelberg (Germany) and Roche (Switzerland)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Roche (Switzerland)

Alternative Name(s)

F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co., Roche Holdings, Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2015		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes