# 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	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
13/09/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
08/12/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
27/11/2015	Cancer			

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

Prof Anthony D. Ho

#### Contact details

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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

## Study design

Randomised controlled trial

#### Primary study design

Interventional

# 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 agressive 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 reproducitve age
- 5. Valid patient approval

# Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

#### Sex

Αll

## 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