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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

Registration date
08/12/2005

Last Edited
27/11/2015

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.klinikum.uni-heidelberg.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
B-cell lymphoma

Interventions
Rituximab maintenance compared to observation

Intervention Type

Drug

Phase
Phase III

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

Primary outcome measure
Event-free survival

Secondary outcome measures
Overall survival, progression-free survival

Overall study start date
24/06/2002

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
174

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)

Sponsor details
University of Heidelberg
Administration Office
INF 672
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Germany
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+49 (0)6221 568001
mathias.witzens-harig@med.uni-heidelberg.de

Sponsor type
Industry

Website

http://www.uni-heidelberg.de

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.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

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?
Results article	results	01/12/2015		Yes	No