Determination of the pharmacokinetics of rituximab and antibodies to rituximab in patients with a B-cell CD20+ malignancy who are treated with rituximab as single agent or rituximab in combination with chemotherapy or are on maintenance therapy with rituximab

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· To get more insight into the pharmacokinetics of rituximab in patients with CD20+ B cell malignancies who are treated with rituximab containing chemotherapy or maintenance therapy with rituximab· To use the results of the data to further improve...

Ethical review	Approved WMO
Status	Pending
Health condition type	Lymphomas non-Hodgkin's B-cell
Study type	Observational non invasive

Summary

ID

NL-OMON31559

Source
ToetsingOnline

Brief title
Pharmacokinetics and antibodies rituximab during standard treatment

Condition

- Lymphomas non-Hodgkin's B-cell

Synonym
B-cell non-Hodgkin lymphoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Geld dat voor het grootste deel via ons instituut vrijgemaakt is voor promotie-onderzoek van mevrouw Ly Tran

Intervention

Keyword: Antibodies, CD20+ B-cell malignancy, Pharmacokinetics, rituximab

Outcome measures

Primary outcome

The results of the determination of the rituximab levels and development of antibodies against rituximab will be correlated to the patient data in a multivariate analysis.

The parameters that will be included into the multivariate analysis are:

Age of the patient, sex, type of CD20+ B-cell malignancy, tumor load, type of chemotherapy if applicable, number of cycles given to the patient, number of maintenance treatment, renal function, blood counts and presence of CD20+ cells in the peripheral blood.

We wish to get answer to the following questions:

· Intra-patient: correlation of the pharmacokinetics with tumor load, the number of cycles given, duration of maintenance treatment, renal function, influence of chemotherapy on the pharmacokinetics of rituximab, if the pharmacokinetics of rituximab come to a steady state situation and if so, is this correlated to tumor load, response, kind of chemotherapy, renal function

· Inter patient: variation between patients with regard to the parameters

mentioned in the intra patient variation and the parameters which determine

this variation.

Secondary outcome

None

Study description

Background summary

The information about the pharmacokinetics of rituximab and development of antibodies against rituximab is almost entirely restricted to patients with CD20+ B-cell malignancies who have been treated with rituximab as single agent, who were rituximab naïve and received only four courses of rituximab. The results of these studies showed that the half life of rituximab was dependent on the tumor load and renal function. There was a considerable inter-patient variation and the half life became longer after several cycles of treatment with diminishing tumor load. In these patients, development of antibodies against rituximab seldom occurred. This is in contrast with patients with auto-immune diseases who are treated with rituximab, like patients with Sjögren*s disease: the half life of the rituximab in these patients is comparable with the half life of normal antibodies and many of these patients develop antibodies against rituximab.
We wish to get more insight into the pharmacokinetics of rituximab and development of antibodies against rituximab when it is combined with chemotherapy or is given as maintenance treatment in patients with CD20+ B-cell malignancies.
The results of this study will be used for possible improvement of the rituximab containing therapies in patients with CD20+ B-cell malignancies and further development of other treatment modalities like radio-immunotherapy with 131I labeled rituximab.

Study objective

· To get more insight into the pharmacokinetics of rituximab in patients with CD20+ B cell malignancies who are treated with rituximab containing chemotherapy or maintenance therapy with rituximab
· To use the results of the data to further improve rituximab containing therapies for patients with CD20+ B-cell malignancies (including radio-immunotherapy with rituximab)
· To gain more knowledge about the development of antibodies against rituximab in patients who are treated with rituximab in combination with chemotherapy or

are on maintenance therapy

Study design

Patients with a CD20+ B-cell malignancy who are treated with rituximab containing regimens or are on maintenance therapy with rituximab will be informed by their treating physicians in line with the rules of good clinical practice about this study. Patients who give their informed consent will be registered into the study. On the day of the treatment with rituximab, 5 ml EDTA blood will be taken before the start of the therapy. The extra 5 ml EDTA blood will be taken for each rituximab containing cycle or for each maintenance treatment until the patient stops with therapy with rituximab. The blood will be taken by the nurses of the fourth floor or the out patient nursery department (dagbehandeling) when they introduce the infusion needle for the administration of rituximab. The blood has to be taken before the rituximab is given to the patient.
Mrs Tran or one of her colleagues collect the blood samples, the blood will be centrifuged and stored at the department of pharmacy at -20 o Celsius.
The samples will be brought to the department of Auto-immune Diseases of Sanquin for the determination of the rituximab levels and antibodies against rituximab.

Study burden and risks

none, 5 ml extra EDTA blood taken before each course of rituximab containing therapy

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

· All patients with a CD20+ B-cell malignancy who are treated with rituximab are eligible for this study.
· Written informed consent

Exclusion criteria

no written informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008

Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL20800.031.07