Vaccination response in lymphoma patients treated with CHOP and rituximab

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To study the immune response to vaccination with influenza virus vaccine, conjugated Hib and pneumococcal vaccine after treatment with rituximab in association with the reconstitution of immune function (in terms of amount of B-cells and...

Ethical review	Not approved
Status	Will not start
Health condition type	Lymphomas non-Hodgkin's B-cell
Study type	Interventional

Summary

ID

NL-OMON32777

Source
ToetsingOnline

Brief title
RIVAC

Condition

- Lymphomas non-Hodgkin's B-cell
- Bacterial infectious disorders

Synonym
B-cell malignancy, lymph node cancer

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: infection, non Hodgkin's lymphoma, rituximab, vaccination

Outcome measures

Primary outcome

Antibody titres against S. pneumoniae and H. influenzae type b (in µg/mL) and the influenza virus before and after vaccination. The association between the reconstitution of immune function after treatment with rituximab (in terms of amount of B-cells and immunoglobulin levels) and the rise in antibody titre.

Secondary outcome

o The effect of the use of growth factor during chemotherapy on the response to vaccination

o The relationship between time since last rituximab-dose and the rise in antibody titre

Study description

Background summary

Rituximab is a chimeric anti-CD20 monoclonal antibody used in combination with chemotherapy for the treatment of non-Hodgkin*s lymphoma (NHL). Following infusion with rituximab, B-cell depletion from the peripheral blood occurs within days. Levels of normal peripheral B-cells remain low for 2-6 months. Because of the immunosuppressive (chemo) therapy, patients are prone to develop infections with encapsulated bacteria such as Streptococcus pneumoniae and Haemophilus influenzae (Hib). Vaccination against these bacteria and the influenza virus is therefore recommended for these immunocompromised patients. Little is known about the effect of rituximab on the response to vaccination. In this study the humoral and cellular immune-response to vaccination is investigated in patients with non-Hodgkin*s lymphoma who were treated with rituximab.

Study objective

To study the immune response to vaccination with influenza virus vaccine, conjugated Hib and pneumococcal vaccine after treatment with rituximab in association with the reconstitution of immune function (in terms of amount of B-cells and immunoglobulin levels).

Study design

The design is a non-randomised cohort study. A total of hundred-forty (140) patients with non-Hodgkin*s lymphoma, who were treated with rituximab in the last twelve months before start of the study and are in remission, will be included.

Intervention

all patients will receive the pneumococcal conjugate vaccine Prevnar®, the Hib conjugate vaccine Act-Hib®, the influenza virus vaccine Influvac® and the pneumococcal polysaccharide vaccine Pneumovax®23. All vaccines will be used in the authorised forms according to existing vaccination protocols in immunocompromised patients.

Study burden and risks

Patients will be vaccinated at three different moments with vaccines that are indicated for this patient group according to existing vaccination protocols. Blood samples will be drawn before the first vaccination and three weeks after each vaccination, so four blood samples will be drawn. If possible, vaccination will be integrated in normal out-patient clinical visits. All vaccines will be used in their authorised forms and for their authorised purpose, therefore no additional risks are to be expected. Patient discomfort might consist of a painful arm/leg after vaccination. Benefit is protection against infections with encapsulated bacteria such as Streptococcus pneumoniae and Haemophilus influenzae (Hib); bacteria which are known to cause serious infections in immunocompromised patients.

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

- Patients with non-Hodgkin's lymphoma, treated with rituximab (approximately 6-8 cycles) and who are in remission.
- Completion of rituximab therapy in the last twelve months before start of the study
- Age 18 years or older
- Signing of informed consent

Exclusion criteria

- Vaccination with Hib or pneumococcal vaccine in the last fifteen months before start of the study
- Fever at time of vaccination
- Previous/known allergic reaction to any of the components of the vaccines given

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	140
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-03-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Not approved

Date:	25-03-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2008-006712-37-NL
CCMO	NL25457.000.08