Efficienty of vaccination in patients with cancer who are treated with chemotherapy.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23415

Source
NTR

Brief title
RITUXIVAC

Health condition

lymphoma, non-hodgkins lymphoma, NHL, vaccination, influenza, humoral response, rituximab.
lymfoom, non-hodgekin's lymfoma, NHL, vaccinatie, influenza, humorale respons, rituximab.

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis Nieuwegein
Source(s) of monetary or material Support: in progress

Intervention

Outcome measures

Primary outcome

Percentage responders.

Secondary outcome

Immunesystem components (amount of memory Bcells, lymphocyte sbsets etc).

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 in 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 might be prone to develop infections with the influenza virus. Vaccination against this virus is, therefore, indicated for these immunocompromised patients. However little is known about the effect of rituximab with chemotherapy in patients with non-Hodgkin lymphoma on the response to vaccination.

Objectives of this study are to investigate what the ideal moment to vaccinate would be, early (after 3-6 months) or late (after 9-12 months) after cessation of rituximab. Secondly to study the immune-response to vaccination with influenza virus vaccine, after treatment with rituximab in relation to the reconstitution of immune-function (in terms of number of B-cells, lymphocyte subsets, immunoglobulin levels and IgG subclasses, CD4+ IFN-alfa production, BAFF, CXCl13 and IL-10).

Study objective

Patients with lymphoma who are treated with rituximab have an increased risk of developing infections. However because of the disease, and because rituximab also diminishes healthy B cells, the humoral response to vaccination may be impaired.

Study design

2-6 months after rituximab treatment or 9-12 months after rituximab treatment.

Intervention

Influenza vaccination.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with non-Hodgkin’s lymphoma, treated with rituximab (with a range of 6-12 cycles) and who are in remission;

2. Completion of rituximab therapy in the last twelve months before start of the study;

3. Age ≥ 18 years;

4. Signing of informed consent.

Controls:

1. Age, sex and co-morbidity matched control who has an indication for influenza vaccination.

Exclusion criteria

1. Completion of rituximab therapy 7-8 months before start of the study;

2. Fever at time of vaccination;

3. Previous/known allergic reaction to any of the components of the vaccines given.

Controls:

1. Immunocompromised persons will be excluded (for example immunosuppressive medication).

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2012
Enrollment:	160
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 38294
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3007
NTR-old	NTR3155
CCMO	NL37320.100.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38294

Study results

Summary results
N/A