Respons to vaccination in patients with cancer of the lympfnodes who are treated with chemotherapy.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27098

Source
NTR

Brief title
Pneumotuxivac

Health condition

pneumoccocus
hemophilus influenza B
vaccination
lymphoma
rituximab

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Antibody titres against S. Pneumonia and H. influenzae type b (in µg/mL) vaccine before and after vaccinations. Titres will be interpreted and classified in responder or non-responder.

Secondary outcome

- Immunoglobulin levels and subclass.
- Lymphocyte subsets (number of B cells and memory-B cells, CD3, CD4, CD8 and NK cells).
- Production of IFN-gamma by CD4+ cells. This will be measured in order to investigate if cellular mediated immune responses are intact after rituximab treatment. - Cytokines and genetic factors (for example BAFF, CXCL13, APRIL) influencing B cell development and survival will be measured in order to determine if there is a correlation between specific cytokines/genetic factors and the observed B-cell depletion/reconstitution.
- Serum rituximab levels.

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 immune suppressive (chemo) therapy, patients are prone to develop infectious complications with Hemophilus infleunza type B (Hib) or S. pneumoniae. There is no data on the infectionrates of S.pneumoniae and Hib in patients with NHL who were treated with chemotherapy and rituximab. However vaccination seems indicated for this patientgroup. Little is known about the effect of rituximab and chemotherapy on the response to pneumoccocal and Hib vaccination.
Objective: To compare the number of responders to vaccination with pneumococcal and conjugated Hib vaccine at different time points after last dose of rituximab, to investigate what the ideal moment of vaccination would be. Secondly to study the immune-response to vaccination with conjugated Hib and pneumococcal vaccine after treatment with rituximab in relation to the reconstitution of immune-function (in terms of number and subsets of B-cells, lymphocyte subsets, immunoglobulin levels and IgG subclasses, CD4+ IFN-gamma production, BAFF, CXCl13 and IL-10).
Study design: The design is a randomised trial. A total of hundred-fifty-two (152) patients with non-Hodgkin's lymphoma, who were treated with rituximab in the last five months before start of the study and are in remission, will be included. Patients will be randomised for early vaccination (six months after rituximab) or late vaccination (twelve months after rituximab). Two and six months after the first vaccination with synflorix (conjugated pneumococcal vaccine) and act-Hib (conjugated Hib vaccine), the second and third vaccination will be given with synflorix and act-Hib and pneumovax (pneumococcal polysaccharide vaccine) and act-Hib respectatively.

Study objective

Patients with non-hodgkins lymphoma who are treated with chemotherapy and rituximab are at risk of developing infections. Vaccination with pneumococcal and Hib vaccines can give protection. However due to rituximab B-cell depletion occurs. It is not known what the optimal moment of vaccination is, at what time the immune system can generate adequate antibody levels.

Study design

Patients will be randomised to start with the vaccination schedule 6 months or 12 months after last dose of rituximab.
At day 0 vaccination will be given, 3 weeks later blood will be drwan.
At 2 months the second vaccination takes place, 3 weeks later blood will be drawn.
At 8 months the third vaccination will be given. 3 week later vblood will be drawn.
At 14 months blood will be drawn.

Intervention

- At the first visit when patients are randomized, blood will be drawn and the first vaccination with Prevnar 13 and Act-Hib will be given.
- 3 weeks later, blood will be drawn.
- 2 months later, the second vaccination with Prevnar 13 and Act-Hib will be given. - 3 weeks after de second vaccination, blood will be drawn.
- 8 months later, the third vaccination with Pneumovax and Act-Hib will be given.
- 3 weeks after the 3rd vaccination, blood will be drawn.
-14 months later, blood will be drawn.

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 five months before start of the study.
3. Age ≥ 18 years.
4. Signing of informed consent.

Exclusion criteria

1. Completion of rituximab therapy >5-6 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.
4. Vaccination with Hib or pneumococcal vaccine in the last fifteen months before start of the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2014
Enrollment:	152
Type:	Anticipated

Ethics review

Positive opinion
Date: 31-01-2014
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39920
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4206
NTR-old	NTR4417
CCMO	NL40482.100.12
OMON	NL-OMON39920

Study results