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

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23415

Bron
Nationaal Trial Register

Verkorte titel
RITUXIVAC

Aandoening

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

Ondersteuning

Primaire sponsor: St. Antonius Ziekenhuis Nieuwegein
Overige ondersteuning: in progress

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage responders.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Influenza vaccination.

Contactpersonen

Publiek

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+31 (0)88 3203000

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38294
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A