

Immunological Monitoring of VZV Vaccination in Patients with Renal Failure versus Healthy Individuals.

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Prophylactic VZV vaccination before transplantation to boost the patient's memory T and B-cell repertoire and thereby reduce the morbidity associated with herpes zoster after transplantation.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25608

Bron

Nationaal Trial Register

Aandoening

renal insufficiency herpes zoster vaccination prevention renal transplantation

Ondersteuning

Primaire sponsor: Erasmus MC Rotterdam

Overige ondersteuning: Erasmus MC Rotterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. VZV-specific IgG and IgM levels;

2. Percentage of VZV-reactive memory CD4+ and CD8+ T-cells.

CD3+ and CD14+ will be isolated from the peripheral blood cells to determine the

percentage of VZV-specific CD4+ and CD8+ T-cells by flowcytometry [14] at the Transplantation Laboratory (7 tubes of 6 ml heparinized blood).

Four samples of blood will be sampled from a vein in the forearm by venapunction by our nurses at day of inclusion (day 0), 1, 3 and 12 months after vaccination. At day 0 and 3 months VZV-specific titres and T-cell reactivity will be performed (8 tubes each time: 48 ml), and 1 and 12 months after vaccination VZV-specific titres and VZV-PCR will be performed (2 tubes: 12 ml).

Toelichting onderzoek

Achtergrond van het onderzoek

40 patients with renal insufficiency (age 50+) on the waitlist for renal transplantation, who are VZV IgG-positive will be vaccinated once with Zostavax, to booster their immune-respons. 40 healthy controls will be donors for living renal transplantation, over the age of 50, who are VZV IgG positive. Both groups will be compared whether they have comparable immune-responses and rise in VZV-specific titres.

Doel van het onderzoek

Prophylactic VZV vaccination before transplantation to boost the patient's memory T and B-cell repertoire and thereby reduce the morbidity associated with herpes zoster after transplantation.

Onderzoeksopzet

T = 0 (time of vaccination);

T = 1 month after vaccination;

T = 3 months after vaccination;

T = 1 year after vaccination (endpoint).

Onderzoeksproduct en/of interventie

One vaccination with Zostavax, subcutaneous. Blood-samples at time T = 0, T = 1 month after vaccination, T = 3 months after vaccination, T = 1 year after vaccination.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age $\geq$ 50 years;
2. Patients on waitlist for living-related kidney transplantation and their donors;
3. Patients at least 1 month prior to kidney transplantation;
4. VZV seropositive before vaccination;
5. Capable of understanding the purpose and risks of the study, fully informed and given written informed consent (signed informed consent form has been obtained).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Use of immunosuppression (inhalation of corticosteroids is allowed);
2. Neomycine allergy;
3. Fever (inclusion: one week no fever);

4. Immunodeficiency due to e.g. acute or chronic leukaemia, lymphoma or HIV;
5. Active tuberculosis.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-12-2012
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	25-01-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37984
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3637
NTR-old	NTR3825
CCMO	NL28557.000.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37984

Resultaten

Samenvatting resultaten

N/A