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

No registrations found.

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

Summary

ID

NL-OMON25608

Source
Nationaal Trial Register

Health condition

renal insufficiency herpes zoster vaccination prevention renal transplantation

Sponsors and support

Primary sponsor: Erasmus MC Rotterdam
Source(s) of monetary or material Support: Erasmus MC Rotterdam

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

N/A

Study description

Background summary

40 patients with renal insufficieny (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 comparible immune-responses and rise in VZV-specific titres.

Study objective

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.

Study design

T = 0 (time of vaccination);

T = 1 month after vaccination;

T = 3 months after vaccination;

T = 1 year after vaccination (endpoint).

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age ≥ 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).

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2012
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-01-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37984
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A