Immunological monitoring of VZV vaccination in patients with renal failure versus healthy individuals

Published: 28-07-2009
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To study if there is a role for prophylactic VZV vaccination prior to transplantation to boost the patients B- and T-cell repertoire and thereby reducing the incidence and morbidity associated with herpes zoster.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON37984

Source
ToetsingOnline

Brief title
Immunological monitoring of VZV vaccination

Condition

- Viral infectious disorders
- Renal disorders (excl nephropathies)

Synonym
herpes zoster, shingles

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Herpes zoster, Kidney transplantation, Prevention, Vaccination

Outcome measures

Primary outcome

VZV-specific IgG and IgM levels from baseline to endpoint (1 year after vaccination)

Percentage of VZV-reactive memory CD4+ and CD8+ T-cells from baseline to endpoint

Secondary outcome

Detection of VZV positive PCR in blood, transplantation will be delayed until PCR is negative

Study description

Background summary

Primary infection with varicella zoster virus (VZV) results in lifelong latent infection of neurons in sensory ganglia from which it may reactivate, resulting in herpes zoster. Herpes zoster is a frequent complication after organ transplantation.

Recently we demonstrated that VZV-specific IgG titres were significantly lower after transplantation compared to prior to transplantation. Questioned is if VZV vaccination in patients prior to renal transplantation gives a similar immunerespons compared with their healthy donors.

Study objective

To study if there is a role for prophylactic VZV vaccination prior to transplantation to boost the patients B- and T-cell repertoire and thereby reducing the incidence and morbidity associated with herpes zoster.

Study design

A single centre, open study in patients on waitlist for living renal transplantation and their living donors.

Intervention

Vaccination with VZV strain to prevent herpes zoster

Study burden and risks

Possible side effects of the vaccination include redness, pain, itching, swelling, warmth or bruising at the injection site, as well as headache.

At study baseline the research nurse will fill in a questionnaire together with the patient.
Blood samples will be collected simultaneously with standard clinical evaluations and usual recurring blood tests following renal transplantation.
Two additional blood tests will be performed compared with standard treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age of patient and donor is 50 years or older
- Patients on waitinglist for living-related kidney transplantation and their donors
- Patients at least 1 month prior to kidney transplantation
- Patient is VZV seropositive before vaccination
- Patient is capable of understanding the purpose and risks of the study, fully informed and given written informed consent

Exclusion criteria

- Use of immunosuppresion (inhalation corticosteroids are allowed)
- Neomycine allergy
- Fever
- Immunodeficiency due to e.g. acute/chronic leukaemia, lymphoma or HIV
- Active tuberculosis

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	15-03-2010
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Zostavax, powder and solvent for suspension for injection

Ethics review

Approved WMO Date:	28-07-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	24-12-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	22-05-2014
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25608
Source: Nationaal Trial Register

Title:

In other registers

Register	ID
EudraCT	EUCTR2009-014268-20-NL
CCMO	NL28557.000.09
OMON	NL-OMON25608