Immunity to varicella-zoster virus in patients before and after lung transplantation

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immune disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON43319

Source
ToetsingOnline

Brief title
VZV and lungTx

Condition

- Immune disorders NEC
- Viral infectious disorders
- Thoracic disorders (excl lung and pleura)

Synonym
herpes zoster, shingles

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: immunity, lung transplantation, vaccination, varicella-zoster virus

Outcome measures

Primary outcome

Cellular immunity is chosen as the primary objective as this measure is known

to be more important than humoral immunity in the defence to VZV.

Main study endpoint will be changes in cellular immunity pre-vaccination, 2

weeks and 3 months after vaccination, and 3 months after lung transplantation.

Secondary outcome

As secondary objectives humoral immunity and control parameters will be

determined. Furthermore, herpes zoster incidence will be registered.

Study description

Background summary

Varicella-zoster virus (VZV) is known to cause varicella or *chickenpox* and herpes zoster (shingles; *gordelroos*). In lung transplant recipients, a herpes zoster incidence of 12.5-20.2% has been described, which is approximately 30 times higher than in the general population and 5 times higher than in those >60 years of age. This incidence rate is higher than for solid organ transplant recipients in general and may be particularly high in lung transplant recipients because of the high doses of immunosuppressive medication they receive.
A live attenuated vaccine to prevent herpes zoster, which is 14 times more potent than the varicella vaccine intended for VZV-seronegative persons, has been registered for use in healthy elderly in the United States of America. This vaccine was shown to reduce the incidence of herpes zoster with 51% and of post-herpetic neuralgia with 67% in people aged 60-70 years. No data are available regarding use of this vaccine in lung transplantation patients.
In the 2016 listing criteria for heart transplantation by the International Society for Heart Lung Transplantation (ISHLT), it is advised to consider

herpes zoster vaccination pre-transplantation.
In the UMCG, because of the high herpes zoster incidence, patients new on the lung transplantation waiting-list will receive VZV vaccination as a part of pre-transplantation work-up. This provides a unique opportunity for studying immunological response to vaccination in this patient group.

Study objective

Objective of the study is to evaluate efficacy of VZV vaccination in lung transplantation patients, intended to prevent morbidity by VZV infection. Efficacy of vaccination will be measured by means of determining cellular immunity to VZV. Cellular immunity is known to be more important than humoral immunity in the defence to VZV. Furthermore, incidence of herpes zoster will be recorded and compared between vaccinated and non-vaccinated patients.

Study design

Cohort study. On multiple time points before and after lung transplantation, and before and after vaccination, blood will be drawn.

Study burden and risks

Participating in this study will not pose a risk to subjects, as participation does not lead to alterations of standard patient care.
The participants will be asked to donate blood. Drawing blood is not considered to be high-risk and in most cases can be combined with blood drawings for routine diagnostic purposes. The study will provide highly interesting information regarding infections in transplantation patients. Very little is known on this topic at the moment.

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

• Provision of written informed consent
• >=18 years of age;(for the part evaluating vaccination)
• Intended administration of VZV vaccine

Exclusion criteria

• Pregnancy;(for the part evaluating vaccination)
• No administration of VZV vaccine due to any reason

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	02-05-2016
Enrollment:	190
Type:	Actual

Ethics review

Approved WMO Date:	10-10-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL56805.042.16

Study results

Date completed:	02-05-2021
Actual enrolment:	105

Summary results
Trial is onging in other countries