An open-label pilot study on the effects of trivalent inactivated influenza vaccination (Influvac®) in patients with hypo- and dysgammaglobulinemia.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23525

Source
NTR

Brief title
VIPID

Health condition

patients with hypo- or dysgammaglobulinemia fullfilling the criteria for primary immunodeficiency as defined by the Pan-American Group for Immunodeficiency and the European Society for immunodeficiencies

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Grant applications are under construction

Intervention

Outcome measures

Primary outcome

Cellular immune responses.

Secondary outcome

1. Humoral immune responses;

2. Side effects.

Study description

Background summary

Hypo- or dysgammaglobulinemia, caused by several primary immunodeficiency syndromes, usually leads to recurrent infections. Vaccination to prevent these infections in general does not result in an adequate generation of protective antibodies in this category of patients. However, for prevention of influenza virus infection, besides protective antibodies T-cell responses have been shown to prevent this infection or to reduce the severity of influenza virus infection.

Although in a number of the primary immunodeficiency syndromes causing hypo- or dysgammaglobulinemia B-cell dysfunction may accompanied by reduced T-cell responses, and treatment with intravenous immunoglobulins alters cellular immunity, no studies have been performed on vaccination against influenza with the currently used subunit vaccines in this category of patients.

In this context, of patients unable to produce protective antibodies, but possibly capable of eliciting protective T-cell responses to influenza virus, we designed a study protocol to determine the cellular immune response following influenza vaccination in patients with hypo- or dysgammaglobulinemia and to determine the usefulness of administering influenza vaccine to this category of patients.

Humoral and T-cell responses will be determined by several proven methods in patients with hypo- or dysgammaglobulinemia at three time points following vaccination with influenza virus subunit vaccine for the season 2006-2007, and compared with the responses measured in healthy controls. A number of 50 patients and 50 matched healthy controls will be included. Patients will be stratified according to the treatment with intravenous immunoglobulins. The two questions to be answered are:

1. Is vaccination with trivalent inactivated influenza vaccine in hypo- and dysgammaglobulinemic patients useful; elicit these patients adequate T-cell responses after influenza vaccination?

2. Is the cellular response dependent on IVIG substitution therapy?

Study objective

Patients with hypo- or dysgammaglobulinemia have comparable cellular immun respons to influenza vaccin as matched healthy volunteers.

Study design

N/A

Intervention

Vaccination with trivalent inactivated influenza vaccin (Influvac®).

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients have to fulfil the diagnostic criteria for primary immunodeficiency as defined by the Pan-American Group for Immunodeficiency and the European Society for immunodeficiencies;

2. Informed consent.

Exclusion criteria

1. Age under 18 years;

2. Current infection, defined as fever in combination with clinical focal signs of infection and the need for therapeutic antibiotic treatment;

3. Pregnancy;

4. Malignancy;

5. Continuous use of immunosuppressive drugs;

6. Known allergy to any substance of Influvac®.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2006
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	08-09-2006
Application type:	First submission

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
NTR-new	NL756
NTR-old	NTR767
Other	: N/A
ISRCTN	ISRCTN31814323

Study results

Summary results
N/A