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

Gepubliceerd: 08-09-2006 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON23525

Bron
NTR

Verkorte titel
VIPID

Aandoening

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

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: Grant applications are under construction

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cellular immune responses.

Toelichting onderzoek

Achtergrond van het onderzoek

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?

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Vaccination with trivalent inactivated influenza vaccin (Influvac®).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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®.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2006
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	08-09-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL756
NTR-old	NTR767
Ander register	: N/A
ISRCTN	ISRCTN31814323

Resultaten

Samenvatting resultaten
N/A