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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
28/12/2006		☐ Protocol		
Registration date 28/12/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 10/06/2021	Condition category	Individual participant data		
10/06/2021	Haematological Disorders			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**Protocol serial number** N/A

# Study information

#### Scientific Title

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

#### Acronym

**VIPID** 

#### **Study objectives**

Patients with hypo- or dysgammaglobulinemia have comparable cellular immune response to influenza vaccine as matched healthy volunteers.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approval received from the Medisch Ethische Toetsingcommissie van het Universitair Medisch Centrum Groningen on the 18th July 2006 (ref: METc2006.124).

#### Study design

Non-randomised, controlled, parallel group, multicentre trial.

#### Primary study design

Interventional

#### Study type(s)

Prevention

# Health condition(s) or problem(s) studied

Hypo- or Dysgammaglobulinemia

#### **Interventions**

Vaccination with trivalent inactivated influenza vaccine (Influvac®)

### Intervention Type

Drug

#### **Phase**

**Not Specified** 

## Drug/device/biological/vaccine name(s)

**Influvac®** 

#### Primary outcome(s)

Cellular immune responses

# Key secondary outcome(s))

- 1. Humoral immune responses
- 2. Side effects

#### Completion date

# **Eligibility**

#### Key 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

## Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

#### Age group

Child

#### Sex

**Not Specified** 

#### Total final enrolment

30

#### Key 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®

#### Date of first enrolment

01/10/2006

#### Date of final enrolment

30/06/2007

# Locations

#### Countries of recruitment

Netherlands

#### Study participating centre

# University Medical Center Groningen

Groningen Netherlands 9700 RB

# Sponsor information

## Organisation

University Medical Center Groningen (UMCG) (The Netherlands)

#### **ROR**

https://ror.org/03cv38k47

# Funder(s)

#### Funder type

Research organisation

#### **Funder Name**

De Cock Stichting (The Netherlands) -a society supporting research in the city of Groningen (http://www.decockstichting.nl/)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2011	10/06/2021	Yes	No