

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

Submission date 28/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/06/2021	Condition category Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

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 measure

Cellular immune responses

Secondary outcome measures

1. Humoral immune responses
2. Side effects

Overall study start date

01/10/2006

Completion date

30/06/2007

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

Age group

Child

Sex

Not Specified

Target number of participants

100

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)

Sponsor details

Department of Internal Medicine

P.O. Box 30001

Groningen

Netherlands

9700 RB

Sponsor type

Hospital/treatment centre

Website

<http://www.rug.nl/umcg/index?lang=en>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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