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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

Registration date
28/12/2006

Overall study status
Completed

Last Edited
10/06/2021

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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