ISRCTN31814323 https://doi.org/10.1186/ISRCTN31814323

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

Contact name
Dr S van Assen

Contact details
University Medical Center Groningen
Department of Internal Medicine
P.O. Box 30001
Groningen
Netherlands
9700 RB
-
s.van.assen@int.umcg.nl

Additional identifiers

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).

Primary study design
Interventional

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

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

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

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