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Assessment of the immunogenicity and safety of the Northern Hemisphere 2010/2011-season influenza vaccine in elderly and young subjects according to European Medicines Agency (EMEA) regulations

Submission date	Recruitment status	[_] Prospectively registered
12/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/01/2011	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/02/2023	Infections and Infestations	[_] Record updated in last year

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
INF-V-A004

Study information

Scientific Title
Assessment of the immunogenicity and safety of the Northern Hemisphere 2010/2011-season influenza vaccine in elderly and young subjects according to European Medicines Agency (EMEA) regulations: an open label, non-randomised uncontrolled safety and efficacy study

Study objectives
The Northern Hemisphere 2010/2011-season influenza vaccine fulfills the European Medicines Agency (EMEA) requirements for re-registration of influenza vaccines.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Medical Ethics Committee (Ethikkommission beider Basel [EKBB]), Switzerland, approved on the 21 April 2010

Study design
Open non-randomised uncontrolled safety/efficacy study

Primary study design
Interventional

Secondary study design
Cohort study

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

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

Interventions
Biological: single dose of trivalent virosomal adjuvanted influenza vaccine (Inflexal® V). Total duration of follow-up: approximately three weeks.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Primary outcome measure
Immunogenicity, assessed by haemagglutination inhibition test; blood to be collected before, one, two and approximately three weeks after vaccination.

Secondary outcome measures
Safety, assessed at baseline and at three weeks after vaccination, including a four-day adverse event questionnaire, soliciting a set of local and systemic adverse events (AEs) according to the European Medicines Agency (EMEA) specifications.

Overall study start date
01/06/2010

Completion date
31/07/2010

Eligibility

Key inclusion criteria
1. Healthy female and male volunteers equal to or older than 18 years of age on the day of enrolment
2. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
110

Key exclusion criteria
1. Pregnancy and lactation
2. Serious adverse reaction to any influenza vaccine

Date of first enrolment
01/06/2010

Date of final enrolment
31/07/2010

Locations

Countries of recruitment
Switzerland

Study participating centre
Covance Clinical Research Unit AG
Allschwil
Switzerland
4123

Sponsor information

Organisation
Crucell Switzerland AG (Switzerland)

Sponsor details
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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Crucell Switzerland AG (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration