ISRCTN40098615 https://doi.org/10.1186/ISRCTN40098615

Assessment of the immunogenicity and safety of the Northern Hemisphere 2008/2009-season influenza vaccine in elderly and young subjects according to European Medicines Agency (EMEA) regulations

Submission date	Recruitment status	[X] Prospectively registered
16/04/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/05/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/04/2009	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

Protocol serial number
INF-V-A002

Study information

Scientific Title

Study objectives
The Northern Hemisphere 2008/2009-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)
Ethics approval received from the Local Medical Ethics Committee (Ethikkommission beider Basel [EKBB]), Switzerland on the 28th February 2008 (ref: 57/08).

Study design
Open non-randomised uncontrolled safety/efficacy study

Primary study design
Interventional

Study type(s)
Prevention

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
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Trivalent virosomal adjuvanted influenza vaccine (Inflexal® V)

Primary outcome(s)
Immunogenicity, assessed by haemagglutination inhibition test; blood to be collected before and approximately three weeks after vaccination.

Key secondary outcome(s))
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.

Completion date
30/08/2008

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

Date of first enrolment
01/06/2008

Date of final enrolment
30/08/2008

Locations

Countries of recruitment
Switzerland

Study participating centre
Swiss Pharma Contract Ltd
Allschwil
Switzerland
4123

Sponsor information

Organisation

Crucell, Berna Biotech Ltd (Switzerland)

Funder(s)

Funder type
Industry

Funder Name
Crucell, Berna Biotech Ltd (Switzerland)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes