

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 (EMA) regulations

Submission date 16/04/2008	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 22/05/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 28/04/2009	Condition category Infections and Infestations	☐ Individual participant data
		☐ Record updated in last year

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

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 (EMA) 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).

Primary study design

Interventional

Study design

Open non-randomised uncontrolled safety/efficacy study

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 (EMA) 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