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Assessment of the immunogenicity and safety of the Northern Hemisphere 2009/2010-season influenza vaccine in elderly and young subjects according to European Medicines Agency (EMEA) regulations

Submission date	Recruitment status	[X] Prospectively registered
28/04/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/05/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/05/2009	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Michael Seiberling

Contact details
Swiss Pharma Contract Ltd
Lettenweg 118
Allschwil
Switzerland
4123

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
INF-V-A003

Study information

Scientific Title

Study objectives
The Northern Hemisphere 2009/2010-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 31th March 2009 (ref: 64/09)

Study design
Open non-randomised uncontrolled safety/efficacy study

Primary study design
Interventional

Secondary study design
Other

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the 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
Drug

Phase
Not Specified

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

Primary outcome measure
Immunogenicity, assessed by haemagglutination inhibition test; blood to be collected before 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
01/06/2009

Completion date
30/08/2009

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
01/06/2009

Date of final enrolment
30/08/2009

Locations

Countries of recruitment
Switzerland

Study participating centre
Swiss Pharma Contract Ltd
Allschwil
Switzerland
4123

Sponsor information

Organisation
Crucell, Berna Biotech Ltd (Switzerland)

Sponsor details
Rehhagstrasse 79
Berne
Switzerland
3018

Sponsor type
Industry

Website
http://www.crucell.com

Funder(s)

Funder type
Industry

Funder Name
Crucell, Berna Biotech Ltd (Switzerland)

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