ISRCTN33950739 https://doi.org/10.1186/ISRCTN33950739

Assessment of the humoral immune response and safety of reduced doses of influenza vaccine administered intradermally compared to intramuscular administration

Submission date
24/09/2007

Recruitment status
No longer recruiting

Registration date
14/11/2007

Overall study status
Completed

Last Edited
16/01/2015

Condition category
Infections and Infestations

[_] 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

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Additional identifiers

Protocol serial number
INF-V-B001

Study information

Scientific Title

Assessment of the humoral immune response and safety of reduced doses of influenza vaccine administered intradermally compared to intramuscular administration

Study objectives
Intradermal administration requires smaller quantities of antigens compared to intramuscular administration to induce a similar immune response.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of Basel (Ethikkommission Beider Basel [EKBB]) (Switzerland) on the 16th July 2007 (ref: 165/07).

Study design
Ramdomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Single-dose, intramuscular (0.5 mL) or intradermal (0.1 mL) administration of influenza vaccine (Inflexal® V).

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Influenza vaccine (Inflexal® V)

Primary outcome(s)
Immunogenicity, assessed by blood tests. Blood was collected before and approximately three weeks after vaccination.

Key secondary outcome(s))
Safety will be assessed at baseline and at 3 weeks after vaccination, including a 4-day adverse event questionnaire, soliciting a set of local and systemic Adverse Events (AEs) according to the European Medicines Agency (EMEA) specifications.

Completion date

30/06/2008

Eligibility

Key inclusion criteria
Healthy volunteers between 18 and 60 years of age.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
1. Pregnancy and lactation
2. Treatment with immunoglobulins or blood transfusions
3. Immunodeficiency
4. History of egg protein allergy/severe atopy/serious adverse reaction to influenza vaccine
5. Previous vaccination against influenza in the past 330 days
6. Participation in another clinical trial
7. Known blood coagulation disorders
8. Acute febrile illness

Date of first enrolment
03/09/2007

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
Switzerland

Study participating centre

Swiss Pharma Contract Ltd.
Allschwil
Switzerland
4123

Sponsor information

Organisation
Berna Biotech AG, Crucell Company (Switzerland)

Funder(s)

Funder type
Industry

Funder Name
Crucell B.V. (Netherlands)

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	results	02/06/2009		Yes	No
Results article	results	23/07/2014		Yes	No