

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

☐ Prospectively registered

☐ Protocol

Registration date

14/11/2007

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

16/01/2015

Condition category

Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

Swiss Pharma Contract Ltd.

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Switzerland

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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).

Primary study design

Interventional

Study design

Randomised controlled trial

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 (EMA) 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