

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	<input type="checkbox"/> Prospectively registered
Registration date 14/11/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/01/2015	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

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 measure

Immunogenicity, assessed by blood tests. Blood was collected before and approximately three weeks after vaccination.

Secondary outcome measures

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.

Overall study start date

03/09/2007

Completion date

30/06/2008

Eligibility**Key inclusion criteria**

Healthy volunteers between 18 and 60 years of age.

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Both

Target number of participants

275

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)

Sponsor details

Rehhagstrasse 79

Berne

Switzerland

3018

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info@bernabiotech.com

Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Crucell B.V. (Netherlands)

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

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