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

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-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

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 (EMEA) 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
-
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