A phase III, observer-blind, multicountry, multicentre study to evaluate the safety, reactogenicity and immunogenicity of GlaxoSmithKline Biologicals' GSK2186877A influenza vaccine administered to adults aged 66 years and older compared to Fluarix* administered to adults aged 19-43 years and 66 years and older, who previously participated in the 111737 study.

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Primary objective is to assess the safety and reactogenicity during the entire study period in subjects aged 66 years (previously enrolled in the FLU NG-036 EXT 025 Y1 study) vaccinated with the FLU NG vaccine or with Fluarix*, and in subjects aged...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON33157

Source
ToetsingOnline

Brief title
FLU NG-039 EXT: FLU-AS25-025 Y2

Condition

- Viral infectious disorders

Synonym
flu, Influenza

Research involving
Human

Sponsors and support

Primary sponsor: GlaxoSmithKline
Source(s) of monetary or material Support: GlaxoSmithKline Biologicals

Intervention

Keyword: elderly, FLU NG, Influenza, revaccination

Outcome measures

Primary outcome

•Solicited local and general symptoms:

-Occurrence, intensity and duration of solicited local AEs during a 7-day follow-up period (i.e. day of vaccination and 6 subsequent days) after vaccination.

-Occurrence, intensity, duration and relationship to vaccination of solicited general AEs during a 7-day follow-up period (i.e. day of vaccination and 6 subsequent days) after vaccination.

•Unsolicited adverse events:

-Occurrence, intensity and relationship to vaccination of unsolicited AEs during a 21-day follow-up period (i.e. day of vaccination and 20 subsequent days) after vaccination.

•Predefined adverse events:

-Occurrence, intensity and relationship to vaccination of AEs with medically attended visit during a 180-day follow-up period (i.e. day of vaccination and 179 subsequent days) after vaccination.

-Occurrence, intensity and relationship to vaccination of AEs of specific interest during the entire study period.

•Serious adverse events:

-Occurrence and relationship to vaccination of SAEs during the entire study period.

Secondary outcome

•Humoral immune response in terms of Haemagglutination Inhibition (HI) antibodies at days 0, 21 and 180.

•Cell-mediated immune (CMI) response at days 0, 21 and 180.

Study description

Background summary

The GlaxoSmithKline Biologicals' strategy to develop an improved influenza vaccine is to use adjuvants to enhance the reduced immunological responses to influenza vaccines in the elderly adults and to do so without compromising vaccine safety. FLU NG vaccine is the final selected formulation of GSK Biologicals* adjuvanted influenza vaccine based on the results of the FLU-AS25-025 PRI study.
Since influenza vaccines are administered every year because of the frequent change in their antigenic composition, the safety and immunogenicity profile of the FLU NG vaccine will be evaluated after repeated vaccination.
In the FLU NG-036 EXT 025 Y1 study, subjects previously enrolled in two specific candidate vaccine groups in the FLU-AS25-025 PRI study were revaccinated with the FLU NG vaccine. Fluarix* was used as a reference.
In this study, subjects of the two specific candidate vaccine groups will be revaccinated for the second time with the FLU NG vaccine and Fluarix* will be used as a reference.

Study objective

Primary objective is to assess the safety and reactogenicity during the entire study period in subjects aged 66 years (previously enrolled in the FLU NG-036 EXT 025 Y1 study) vaccinated with the FLU NG vaccine or with Fluarix*, and in subjects aged 19-43 years (previously enrolled in the FLU NG-036 EXT 025 Y1 study) vaccinated with Fluarix*.

Study design

A phase III, observer-blind, multicountry, multicentre study conducted in three countries recruiting a maximum of 526 subjects. Subjects will receive the same vaccine as during the previous study, either FLU NG or Fluarix*. The treatment is observer blind for subjects aged 66 years or older and open for subjects aged 19-43 years.
Duration of the study is six months. The vaccination schedule is one intramuscular injection at day 0. Bloodsamples will be collected at three visits, day 0, day 21 and day 180. A phone contact is scheduled at day 90.

Intervention

Intramuscular injection of the study vaccine or comparator at day 0.

Study burden and risks

Fluarix* may cause adverse events such as local reactions and mild general symptoms. FLU NG may cause the same adverse events, however the reactogenicity of FLU NG has shown to be higher when compared to Fluarix. Results from previous studies show that FLU NG has an acceptable safety profile and is well tolerated by subjects aged 65 years and older. Risks related to FLU NG vaccination may partially be unknown. Risks related to the blood drawing procedures are low and considered to be acceptable.
All subjects will receive an active vaccine and will benefit from partial protection against flu.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Subjects who the investigator believes that they can and will comply with the requirements of the protocol (e.g., completion of the diary cards, return for follow-up visits, reporting by phone) should be enrolled in the study.
2. A male or female aged 19-43 years or *66 years at the time of the vaccination and who participated in the 111737 study and completed the 6-month follow-up.
3. Written informed consent obtained from the subject.
4. Free of an acute aggravation of the health status as established by clinical evaluation (medical history and physical examination) before entering into the study.
5. Female subjects of non-childbearing potential may be enrolled in the study. Female subjects of childbearing potential may be enrolled in the study if the subject:
•has practiced adequate contraception for 30 days prior to vaccination, and
•has a negative pregnancy test on the day of vaccination, and
•has agreed to continue adequate contraception for 2 months after the vaccination.

Exclusion criteria

1. Use of any investigational or non-registered product (drug or vaccine) other than the study vaccine(s) within 30 days prior to vaccination, or planned use during the study period.
2. Administration of other licensed vaccines within 2 weeks (for inactivated vaccines) or 4 weeks (for live vaccines) prior to enrolment in this study. Planned administration of an influenza vaccine other than the study vaccines or of a vaccine not foreseen in the study

protocol during the entire study period.
3. Vaccination against influenza since January 2009 with a seasonal influenza vaccine.
4. Chronic administration (defined as more than 14 days) of immunosuppressants or other immune-modifying drugs within six months prior to the administration of the study vaccine. (For corticosteroids, this will mean prednisone, or equivalent, *20 mg/day. Inhaled and topical steroids are allowed.)
5. Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required).
6. History of hypersensivity to a previous dose of influenza vaccine.
7. History of allergy or reactions likely to be exacerbated by any component of the vaccine(s).
8. Acute clinically significant pulmonary, cardiovascular, hepatic, renal, neurological and psychiatric disorders, as determined by clinical evaluation (medical history and physical examination) or pre-existing laboratory screening tests.
9. Acute disease and/or fever at the time of enrolment. Fever is defined as temperature >=37.5°C on oral setting. Subjects with a minor illness (such as mild diarrhoea, mild upper respiratory infection) without fever may be enrolled at the discretion of the investigator.
10. Administration of immunoglobulins and/or any blood products within the three months preceding the administration of the study vaccine or planned administration during the study.
11. Any medical conditions in which IM injections are contraindicated
12. Pregnant or lactating female.
13. Female planning to become pregnant or planning to discontinue contraceptive precautions.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2009

Enrollment:	105
Type:	Actual

Ethics review

Approved WMO Date:	07-07-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	07-09-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	17-09-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2009-012188-32-NL

Register	ID
CCMO	NL28615.000.09