A phase IV, open label, randomized, multicountry study to evaluate immunogenicity and safety of GSK Biologicals' seasonal (2010-2011) influenza vaccine Fluarix in children previously vaccinated with GSK Biologicals' H1N1 vaccine (Pandemrix)

Published: 09-08-2010
Last updated: 04-05-2024

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

Summary

ID

NL-OMON34465

Source
ToetsingOnline

Brief title
FLU D-PAN H1N1-AS03-042

Condition

- Viral infectious disorders

Synonym
flu, influenza

Research involving
Human

Sponsors and support

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

Intervention

Keyword: children, H1N1, influenza, vaccine

Outcome measures

Primary outcome

Humoral immune respons against H1N1 in subjects in the Fluarix group.

Secondary outcome

- occurence, intensity and duration of local and general adverse events 28 days

after each vaccination.

- occurence, intensity and duration of serious adverse events and potential

immune-mediated diseases during the entire study period.

- humoral immune respons against all three strains in all subjects.

Study description

Background summary

During April 2009 the first cases of novel influenza A (H1N1) were reported. Vaccination is considered the most effective means in protecting against the pandemic virus. Several manufacturers have developed a vaccine. GlaxoSmithKline Biologicals' vaccine Pandemrix has been used in many European countries. In the Netherlands this vaccine has been given to, amongst others, children in the age of 6 months to 3 years old as part of a national vaccinatie campaign. The European Medicines Agency (EMA) has issued a European Paediatric Investigation Plan to enforce manufacturers of pandemic vaccines to further investigate the immune respons and safety against novel influenza A (H1N1). The current study

is proposed within this framework.

Study objective

The objective of this study is to evaluate the immune respons against the H1N1 strain following vaccination with the first dose of trivalent inactivated influenza virus vaccine (Fluarix) in subjects previously vaccinated with 2 doses of H1N1 adjuvanted vaccine (Pandemrix).

Study design

A phase IV, open-label, randomized, controlled, multi-country study with 360 subjects in two parallel groups. The study group is vaccinated with two doses of Fluarix at day 0 and day 28. The control group is vaccinated with Havrix junior at day 0 and month 6. Reactions to the vaccine are collected through diary cards. Four weeks after each vaccination (day 28 and dag 56) a safety visit is scheduled to collect adverse events. Prior to each vaccination (day 0 and day 28) and at month 6 a blood sample is taken to measure antibody titers. In case of influenza-like illness, defined as fever and/or cough or sore throat, a swab is collected. During the entire study period serious adverse events and potential immune-mediated diseases are collected.

Intervention

Two doses of Fluarix at day 0 and 28 or two doses of Havrix junior at day 0 and month 6.

Study burden and risks

Risks are mainly related to vaccination. Both Fluarix and Havrix junior can cause adverse events like local reactions and mild general symptoms. Serious adverse events like allergical reactions can occur but are very rare.
Blood sampling can be a burden and can cause mild bruising for example.

Contacts

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GlaxoSmithKline

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GlaxoSmithKline

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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

*Subjects having previously been immunized with two 0.25 mL doses of Pandemrix (half dose), given at least 21 days apart, at the age of 6 months to 9 years inclusive at the time of first vaccination.
*Subjects having received the last dose of Pandemrix at least six months prior to study enrolment.
*Subjects who the investigator believes that parent(s)/Legally Acceptable Representative(s) [LAR(s)] can and will comply with the requirements of the protocol (e.g. completion of the diary cards, return for follow-up visits, be available for telephone/fax contacts).
*Written informed consent obtained from the parent(s)/LAR(s) of the subjects.
*Healthy subjects as established by medical history and clinical examination before entering into the study.
*Parent/LAR with access to a consistent means of telephone contact, land line or mobile, but NOT a pay phone or other multiple-user device (i.e., a common-use phone serving multiple rooms or apartments).

Exclusion criteria

*Active participation in other clinical trials.
*Use of any investigational or non-registered product (drug or vaccine) other than the study vaccine within 30 days preceding the first dose of the study vaccine or planned use during the study period.
*Planned administration of any vaccine 30 days prior and 30 days after any study vaccine administration.
*Chronic administration (defined as more than 14 days) of immunosuppressants or other

immune-modifying drugs within three months prior to enrolment in this study or planned administration during the study period. For corticosteroids, this will mean prednisone * 0.5 mg/kg/day, or equivalent. Inhaled and topical steroids are allowed.
*Acute disease and/or fever at the time of enrolment:
-Fever is defined as temperature * 37.5°C on oral, axillary or tympanic setting, or * 38.0°C on rectal 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.
*Any confirmed or suspected immunosuppressive or immunodeficient condition based on medical history and physical examination (no laboratory testing required).
*Acute or chronic, clinically-significant pulmonary, cardiovascular, hepatic or renal functional abnormality, as determined by medical history and physical examination.
*Administration of immunoglobulins and/or any blood products within the three months prior to the enrolment in this study, or planned use during the study.
*Any known or suspected allergy to any constituent of influenza vaccines (including egg proteins or mercurial preservatives); a history of anaphylactic-type reaction to consumption of eggs; or a history of severe adverse reaction to a previous influenza vaccine.
*History of seizures (subjects who have had a single uncomplicated febrile convulsion in the past could be included) or progressive neurological disease.
*Subjects having received an H1N1v pandemic vaccine other than Pandemrix or having received the 2010/2011 seasonal influenza vaccine.
*Child in care.

Study design

Design

Study phase:	4
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):	15-09-2010

Enrollment:	120
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Fluarix
Product type:	Medicine
Brand name:	Havrix junior

Ethics review

Approved WMO Date:	09-08-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-09-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2010-020330-26-NL
CCMO	NL32843.098.10