An open, phase II long term extension study to evaluate the immune responses to and safety of GSK Biologicals' candidate herpes zoster vaccine, (gE/AS01B), at Months 48, 60 and 72 post-vaccination in healthy subjects aged 60 years of age and older.

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The purpose of this long-term follow-up (LTFU) study (ZOSTER-024) is to evaluate the cell-mediated and humoral immune responses of subjects who previously participated in study ZOSTER-003 and who were in the group receiving 2 doses of 50µg gE/AS01B...

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

Summary

ID

NL-OMON36034

Source
ToetsingOnline

Brief title
ZOSTER-024

Condition

- Viral infectious disorders
- Skin and subcutaneous tissue disorders

Synonym

herpes zoster, shingles

Research involving
Human

Sponsors and support

Primary sponsor: GlaxoSmithKline
Source(s) of monetary or material Support: GlaxoSmithKline B.V.

Intervention

Keyword: elderly, herpes zoster, immune responses, zoster vaccine

Outcome measures

Primary outcome

1) Cell-Mediated Immunity (CMI) in terms of frequencies of antigen-specific CD4

T cells at Months 48, 60 and 72

2) Antigen-specific Antibody (Ab) concentrations at Months 48, 60 and 72

Secondary outcome

1) Occurrence of Serious Adverse events (SAEs)

2) Occurrence of pre-defined Adverse events (AEs), i.e. herpes zoster episodes

and Potential Immune-Mediated Diseases (pIMDs)

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Study description

Background summary

Herpes Zoster (shingles) is an illness that occurs due to reactivation of the latent varicella-zoster virus (VZV), which remains in the body after getting chickenpox during childhood. Shingles most commonly occurs in the elderly: 1

out of every 2 persons at the age of 85 has developed shingles during their lifetime. Treatment options include the use of antiviral drugs, which prevent worsening of the disease, and painkilling medication. Zostavax, a vaccine which has been approved for use in the United States, only partially prevents shingles, and is less suitable for persons aged 70 and older, and/or persons with impaired immunity. GSK Biologicals is therefore developing a new shingles vaccine which contains immunostimulants.

The proposed study is a follow-up to the previous Zoster-003 study (CCMO number NL14818.000.06), which compared different formulations of the candidate vaccine against herpes zoster. One of these formulations, 50µg gE/AS01B, has been chosen for use in future studies.

Study objective

The purpose of this long-term follow-up (LTFU) study (ZOSTER-024) is to evaluate the cell-mediated and humoral immune responses of subjects who previously participated in study ZOSTER-003 and who were in the group receiving 2 doses of 50µg gE/AS01B. Long term safety of the study vaccine administered in ZOSTER-003 will also be evaluated.

Study design

Phase II, open-label, multi-centric , single group study.

Intervention

not applicable

Study burden and risks

Burden: Subjects will be asked about their medical history. They will undergo a history-directed physical examination once. Subjects are asked to report Serious Adverse Events throughout the study (2 years). Blood samples will be collected on each of the 3 visits (30 ml per visit, once a year).

The burden for subjects in this study is low. Collection of blood samples causes some discomfort, but at an acceptable level. Subjects contribute to the development of a possibly better vaccine against herpes zoster.

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 can and will comply with the requirements of the protocol (e.g. return for follow-up visits)
2) Previous participation in study ZOSTER-003 as a member of the 50µg gE/AS01B vaccine group
3) Written informed consent obtained from the subject.

Exclusion criteria

1) Having participated in another study at any time after ZOSTER-003 study end in which the subject was exposed to an investigational or non-investigational product (pharmaceutical product or device) or; concurrently participating in another clinical study, at any time during the study period, in which the subject has been or will be exposed to an investigational or a non-investigational product (pharmaceutical product or device)
2) Administration of immunoglobulins and/or any blood products within the 3 months preceding the first blood draw
3) Having received a vaccine containing 3-O-desacyl-4*-Monophosphoryl Lipid A (MPL) and/or Quillaja saponaria Molina, fraction 21 (QS21), any time after ZOSTER-003 study end

4) Having received a vaccine against HZ any time after ZOSTER-003 study end
5) Subject who did not receive a complete vaccination course of 2 doses of 50µg gE/AS01B in study ZOSTER-003

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-04-2011
Enrollment:	18
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	gE recombinant protein formulated in AS01B Adjuvant System

Ethics review

Approved WMO Date:	07-02-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	08-03-2011

Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	22-03-2011
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-09-2012
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	06-11-2012
Application type:	Amendment
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	EUCTR2010-022248-19-NL
CCMO	NL35579.000.11