A Phase IV Clinical Trial to Evaluate the Safety and Tolerability of ZOSTAVAX in Subjects >=60 Years of Age

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The objective of the study is to evaluate the general safety of ZOSTAVAX* in subjects >=60 years of age.

Ethical review	Not approved
Status	Will not start
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON31293

Source
ToetsingOnline

Brief title
Safety and Tolerability of ZOSTAVAX in Subjects >=60 Years of Age

Condition

- Viral infectious disorders

Synonym
Herpes Zoster; shingles

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Herpes Zoster, Shingles, Vaccination, Zostavax

Outcome measures

Primary outcome

The proportion of subjects reporting serious clinical adverse experiences

through Day 42 postvaccination.

Secondary outcome

The proportion of subjects reporting serious clinical adverse experiences

during the entire 6-month postvaccination

follow-up period.

Study description

Background summary

The purpose of the current study is to accumulate additional safety data on the administration of ZOSTAVAX* in subjects >=60 years of age. This will be done by evaluating the relative risk of developing serious clinical adverse experiences for 42 days and 6 months postvaccination in subjects who receive ZOSTAVAX* and those who receive placebo.

In previous clinical studies, including the Protocol 004 (Shingles Prevention Study), the safety, efficacy, and immunogenicity of ZOSTAVAX* were evaluated in subjects >=60 years of age. Protocol 004 demonstrated that ZOSTAVAX* is highly efficacious in preventing HZ and its complications, and that the benefit of vaccination persists through 4 years of follow-up in subjects 60 years of age and older. Furthermore the data from that study showed that the relative risk of developing one or more Serious Adverse Experiences was somewhat lower in the subjects 70 to 79 years of age (0.87 vs. 1.12 for ubjects 60 to 69 years of age and 1.36 for subjects >=80 years of age). To further investigate this observation, the current study will be stratified to target an enrollment of 15% of subjects >=80 years of age.

Study objective

The objective of the study is to evaluate the general safety of ZOSTAVAX* in subjects >=60 years of age.

Study design

This study is a randomized, double-blind (with in-house blinding procedures), placebocontrolled multicenter trial to evaluate the general safety of ZOSTAVAX* in subjects >=60 years of age. Approximately 12,000 subjects will be randomized in a 1:1 ratio to receive a single dose of either ZOSTAVAX* or placebo. Enrollment will be stratified by subject age (with a target of 85% of subjects 60 to 79 years of age and 15% of subjects >=80 years of age).

Subjects will be followed for serious clinical adverse experiences for 42 days postvaccination (primary safety period) and for 6 months postvaccination by telephone contact (secondary safety period). Subjects will be educated and instructed to call the study site immediately, at any time during the study, if they experience a clinical adverse experience that results in a hospitalization, prolongs a hospitalization, is a cancer or an overdose, or is another severe, unexpected, or life-threatening event that could potentially be considered serious.

Subjects will also be called by the study staff at 6 weeks, 4 months, and 6 months postvaccination, using a prespecified telephone script, to determine if the subject had a previously-unreported clinical adverse experience that met one or
more criteria for a serious adverse experience.

Intervention

ZOSTAVAX* or placebo will be administered as a ~0.65-mL subcutaneous injection, preferably in the deltoid region of the nondominant arm.

Study burden and risks

Subjects will be seen by the investigator once for vaccination with the study medication. Subsequently, subjects will be asked to call the investigator when they experience a possible Serious Adverse Event. Subjects are phoned by the investigator as well after 4 weeks, 4 months and 6 months, to ensure that all Serious Adverse Events are recorded.

In previous clinical trials with Zostavax, the following most common adverse experiences were observed: injection-site adverse experiences, such as redness, swelling, pain/sensitivity, itching, bruising, warmth; headache; rash resembling chicken pox.

Contacts

Public
Merck

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Merck

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

(see protocol page 20 for complete text of criteria);- Age >=60 Years
- Signed informed consent form
- Afebrile on day of vaccination
- Females must be postmenopausal or have negative pregnancy test

Exclusion criteria

(see protocol page 20 for complete text of criteria);1. A history of allergic reaction to any vaccine component
2. Prior receipt of any varicella or zoster vaccine.
3. Any live virus vaccine administered within 4 weeks prevaccination or scheduled

during the 42-day postvaccination period.
4. Any inactivated vaccine, except for influenza vaccine, administered within 7 days prevaccination or scheduled during the 42-day postvaccination period
5. Subject is pregnant or breastfeeding.
6. Participation in an investigational drug or vaccine study within the last 30 days prior to enrollment or expected during the 42-day postvaccination period.
7. An intercurrent illness (including active untreated tuberculosis) that might interfere with the interpretation of the study
8. Use of immunosuppressive therapy.
9. Known or suspected immune dysfunction that is caused by a medical condition or any other cause. Subjects with a history of cancer who are not on active treatment and are not thought to be immunosuppressed at enrollment will be eligible for enrollment.
10. Any concomitant use of nontopical antiviral therapy with activity against herpesviruses.
11. Any other reason that in the opinion of the investigator might interfere with the evaluation required by the study.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	750
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-09-2007
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Not approved

Date:	22-02-2008
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	EUCTR2007-000343-10-NL
CCMO	NL19058.000.07