An open-label, randomised, comparative, multi-centre study of the immunogenicity and safety of a 1-dose regimen and different 2-dose regimens of a Zoster vaccine (Live), ZOSTAVAX, in subjects >= 70 years of age

Published: 06-08-2007
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Primary objectivesImmunogenicityTo demonstrate that a second dose of ZOSTAVAX® elicits higher varicella-zoster virus (VZV) antibody titres than a first dose of ZOSTAVAX® whether given as a 0-1 month schedule or as a 0-3 month schedule in subjects...

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

Summary

ID

NL-OMON31421

Source
ToetsingOnline

Brief title
Zostavax-study

Condition

- Viral infectious disorders

Synonym
Herpes Zoster, Shingles

Research involving

Human

Sponsors and support

Primary sponsor: Sanofi Pasteur MSD S.N.C.
Source(s) of monetary or material Support: Sanofi Pasteir MSD

Intervention

Keyword: immunogenicity, Open-label, safety, Zoster vaccin

Outcome measures

Primary outcome

Primary objectives

Immunogenicity

To demonstrate that a second dose of ZOSTAVAX® elicits higher varicella-zoster virus (VZV) antibody titres than a first dose of ZOSTAVAX® whether given as a 0-1 month schedule or as a 0-3 month schedule in subjects >=70 years of age as measured at 4 weeks post-vaccination

Secondary outcome

Secondary Objectives

Immunogenicity

• To summarise the VZV antibody titres 4 weeks post-vaccination after a 1-dose regimen and 4 weeks post-vaccination after each dose of each 2-dose regimen of ZOSTAVAX® administered to subjects >=70 years of age

• To compare the VZV antibody titres at 12 months after completion of a 1-dose regimen with the VZV antibody titres at 12 months after completion of each 2-dose regimen of ZOSTAVAX® administered to subjects >=70 years of age

• To summarise the VZV antibody titres annually at 24 and 36 months after

completion of a 1-dose regimen and at 24 and 36 months after completion of each

2-dose regimen of ZOSTAVAX® administered to subjects >=70 years of age

Safety

• To assess the safety profile of a 1-dose regimen and the safety profile of

each 2-dose regimen of ZOSTAVAX® administered to subjects >=70 years of age

Study description

Background summary

PAge 16-17 of the protocol

Study objective

Primary objectives
Immunogenicity
To demonstrate that a second dose of ZOSTAVAX® elicits higher varicella-zoster virus (VZV) antibody titres than a first dose of ZOSTAVAX® whether given as a 0-1 month schedule or as a 0-3 month schedule in subjects >=70 years of age as measured at 4 weeks post-vaccination

Secondary Objectives
Immunogenicity
• To summarise the VZV antibody titres 4 weeks post-vaccination after a 1-dose regimen and 4 weeks post-vaccination after each dose of each 2-dose regimen of ZOSTAVAX® administered to subjects >=70 years of age
• To compare the VZV antibody titres at 12 months after completion of a 1-dose regimen with the VZV antibody titres at 12 months after completion of each 2-dose regimen of ZOSTAVAX® administered to subjects >=70 years of age
• To summarise the VZV antibody titres annually at 24 and 36 months after completion of a 1-dose regimen and at 24 and 36 months after completion of each 2-dose regimen of ZOSTAVAX® administered to subjects >=70 years of age
Safety
• To assess the safety profile of a 1-dose regimen and the safety profile of each 2-dose regimen of ZOSTAVAX® administered to subjects >=70 years of age

Study design

This is an open-label, randomised, comparative, multi-centre study with 3

groups

Intervention

Randomisation will be done using a 1:1:1 ratio in 3 groups as follows:
Group 1: ZOSTAVAX® at Day 0 only
Group 2: ZOSTAVAX® at Day 0 and Month 1 (Day 28 to Day 35)
Group 3: ZOSTAVAX® at Day 0 and Month 3 (Day 82 to Day 98)

Study burden and risks

According to the clinical development programme of Zostavax®, some very common adverse events, i.e. occurrence equal or greater to 1 case in 10 administrations, are erythema, pain/tenderness and swelling at injection site.

Other events occurring for more than 1 case in 100 administrations but less than 1 case in 10 administrations are haematoma, itching (i.e. pruritus), warmth at injection site and headache.

As with any vaccination, there is a rare possibility of an allergic reaction. This may cause a severe narrowing of the air passages and breathing difficulties.

Additionally, taking blood samples may be associated with some inconveniences, such as slight pain and bruises from needle punctures.

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

70 years or older, varicella history-positive or residence for > 30 years in a country with endemic VZV infection

Exclusion criteria

Febrile within the last 72 hours before vaccination, history of hypersensitivity/anaphylactoid reaction to ZOSTAVAX components including gelatine or neomycin, prior herpes-zoster episode clinically diagnosed by a physician

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:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2007
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	06-08-2007
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	08-08-2007
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-02-2008
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	29-06-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-07-2009
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	EUCTR2007-000744-28-NL
CCMO	NL18285.000.07