Observational study to assess frailty of subjects during ZOSTER-006 and ZOSTER-022 and HZ efficacy, immunogenicity and safety of HZ/su by frailty status (ZOSTER-064)

First published: 03/12/2020

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS38374

Study ID

38630

DARWIN EU® study

No

Study countries

Australia

Brazil

Canada
Czechia
Estonia
Finland
France
Germany
Hong Kong
Italy
Japan
Korea, Republic of
Mexico
Spain
Sweden
Taiwan
United Kingdom
United States

Study description

As part of the ZOSTER-006 and ZOSTER-022 pivotal trials of the HZ/su vaccine, all study participants completed quality of life (QoL) questionnaires. The only questionnaires encoded into the data base were those from participants who developed a suspected shingles episode during the study. The purpose of this study is to allow for the encoding and analysis of questionnaires for all subjects enrolled in ZOSTER-006 and ZOSTER-022. The aim is to assess the baseline frailty of subjects enrolled in these studies and to investigate whether this population is representative of the general population.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 171 centres are involved in the study

Contact details

Study institution contact

Call Center EU Clinical Trials
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Study contact

Vx.publicdisclosureglobal@gsk.com

Primary lead investigator

Call Center EU Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 02/02/2018

Study start date
Actual: 05/06/2018

Date of final study report
Actual: 31/10/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-204878-protocol-redact.pdf (1.3 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Other

If ‘other’, further details on the scope of the study

To determine, by evaluation of frailty, if the study population is representative of the general population

Data collection methods:

Primary data collection

Main study objective:

To assess the baseline frailty of subjects enrolled in the ZOSTER-006 and ZOSTER-022 studies.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

This is a retrospective, observational study, therefore no new subjects will be enrolled in this study

Study drug and medical condition

Medical condition to be studied

Herpes zoster

Population studied

Short description of the study population

Adults aged ≥50 years of age who participated in either ZOSTER006 or ZOSTER-022.

Subjects who were excluded from all analyses from ZOSTER-006 and ZOSTER022 were excluded.

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

25.000

Study design details

Outcomes

The primary outcome of this study is the assessment of baseline frailty status of subjects enrolled in Zoster 006 and Zoster 022. •SF-36 and EQ-5D scale scores at months 0, 14, 26 and 38. •Confirmed HZ cases during the entire study period (3 to 5 year period following Day 0). •Herpes Zoster Burden of Illness Score, by Frailty Status during the entire study period. •Solicited local and general AE,

Unsolicited AE, Serious Adverse Events (SAEs) and Potential Immune-Mediated Diseases (pIMDs). •Humoral Immunogenicity.

Data analysis plan

An analysis will be carried out at the end of the study.

Documents

Study results

gsk-204878-clinical-study-report-redact-01.pdf (8.52 MB)

gsk-204878-clinical-study-report-redact-02.pdf (9.49 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Database consisting of the Zoster 006 (NCT01165177) and Zoster 022 (NCT01165229) study data.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No