Prevalence of immunology testing in patients treated with alglucosidase alfa with significant hypersensitivity/anaphylactic reactions (ALGMYC07390)

First published: 03/08/2015

Last updated: 25/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10526

Study ID

37523

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

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Institution

Contact details

Study institution contact

Team Transparency contact-us@sanofi.com

Study contact

contact-us@sanofi.com

Primary lead investigator

Stéphanie Tcherny-Lessenot

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/03/2015

Actual: 23/03/2015

Study start date

Planned: 31/12/2015

Actual: 01/07/2016

Data analysis start date

Planned: 30/09/2016

Actual: 30/09/2016

Date of interim report, if expected

Planned: 31/12/2016

Actual: 23/12/2016

Date of final study report

Planned: 31/08/2019

Actual: 12/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Genzyme Europe B.V., The Netherlands

Study protocol

rdct-ALGMYC07390_study protocol_V3_final 14dec2015_approved-PDFA.pdf

(320.63 KB)

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)

Other study registration identification numbers and links

ALGMYC07390

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

This study aims to determine the prevalence of patients treated with alglucosidase alfa with significant hypersensitivity/anaphylactic reactions who undergo immunology testing. The difference in prevalence of testing between the two periods of 3 years before and after the implementation of the revised SIP (version 8.2) will be assessed as a measure of effectiveness of risk minimization measures.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

MYOZYME

Study drug International non-proprietary name (INN) or common name

ALGLUCOSIDASE ALFA

Anatomical Therapeutic Chemical (ATC) code

(A16AB07) alglucosidase alfa

alglucosidase alfa

Medical condition to be studied

Glycogen storage disease type II

Population studied

Short description of the study population

The population included all patients treated with alglucosidase alfa with a spontaneously reported significant hypersensitivity/anaphylactic reaction to the Sanofi Genzyme Pharmacovigilance adverse event database during the study period within European countries in which the revised SIP had been distributed by March 31, 2016.

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

1

Study design details

Data analysis plan

The primary analysis population will be patients from Europe.The analyses will be descriptive and will be made on all patients available in the databases at

time of each analysis. The prevalence of testing will be provided for each period (3-year period before and 3-year period after implementation of the revised SIP). The results will be displayed by 3-year period before and after the implementation of revised SIP and by country in Europe when appropriate.

Documents

Study results

rdct-alglucosidase-alfa-PASS-immunology-testing_finalreport_abstract_FINAL 08 June 2020-PDFA.pdf(159.55 KB)

Data management

Data sources

Data source(s), other

- Sanofi Genzyme Pharmacovigilance adverse event database
- Genzyme Clinical Specialty Laboratory database

Data sources (types)

Other

Spontaneous reports of suspected adverse drug reactions

Data sources (types), other

Routine performance of immunology testing since treatment start

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