# 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

**PURI**

https://redirect.ema.europa.eu/resource/37523

**EU PAS number**

EUPAS10526

**Study ID**

37523

**DARWIN EU® study**

No

**Study countries**

☐ France

☐ Germany

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Sanofi

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

# Contact details

**Study institution contact**

Team Transparency

**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

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**Study start date**
Planned: 31/12/2015

Actual: 01/07/2016

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**Data analysis start date**
Planned: 30/09/2016

Actual: 30/09/2016

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**Date of interim report, if expected**
Planned: 31/12/2016

Actual: 23/12/2016

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**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

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**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.

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**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)

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**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