# 241302: POST-MARKETING non-interventional safety evaluation of obizur in the treatment of bleeding episodes for patients with acquired hemophilia A (241302: US Post-Marketing Safety Study)

**First published:** 17/08/2020

**Last updated:** 02/04/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS36659

**Study ID**

43028

**DARWIN EU® study**

No

**Study countries**

☐ United States

**Study description**

The overall objective is to enroll patients with acquired hemophilia A (AHA) who are prescribed and treated with Obizur, to assess safety, and to describe factors related to safety, utilization and effectiveness in a real-world setting.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### Takeda

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

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

Institution

### Multiple centres: 18 centres are involved in the study

## Contact details

**Study institution contact**

Call Center Shire clinicaltransparency@shire.com

**Study contact**

clinicaltransparency@shire.com

**Primary lead investigator**

Call Center Shire

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Actual: 29/10/2015

**Study start date**
Actual: 30/12/2015

**Data analysis start date**
Actual: 07/06/2019

**Date of final study report**
Actual: 22/06/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Baxalta Innovations GmbH, now part of Takeda and Baxalta US Inc.

# Study protocol

241302-protocol-original-redact.pdf (831.52 KB)

241302-protocol-amendment-3-redact.pdf (882.4 KB)

# Regulatory

**Was the study required by a regulatory body?**

Yes

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

EU RMP category 3 (required)

# Other study registration identification numbers and links

NCT02610127,https://clinicaltrials.gov/ct2/show/NCT02610127?term=NCT02610127&draw

# Methodological aspects

# Study type

# Study type list

**Study topic:**

Human medicinal product

Disease /health condition

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

**Main study objective:**

The primary objective is to determine the incidence of therapy-related serious adverse events (SAEs) in patients with AHA who are prescribed and treated with Obizur in routine clinical practice.

## Study Design

**Non-interventional study design**

Other

**Non-interventional study design, other**

Prospective and retrospective post-marketing safety surveillance study

## Study drug and medical condition

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

ANTIHEMOPHILIC FACTOR (RECOMBINANT) FORMULATED WITH SUCROSE

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**Medical condition to be studied**

Acquired haemophilia

# Population studied

**Short description of the study population**

Patients with acquired hemophilia A (AHA) were eligible for participation in this study if they were treated with Obizur in a hospital setting. All patients were required to be prescribed Obizur by a physician, prior to the decision to enroll in the study.

Inclusion Criteria

Subjects who meet ALL of the following criteria are eligible for this study:

1. Subject is ≥18 years of age at the time of informed consent.
2. Subject has AHA, and is being treated/was treated with Obizur.
3. Subject or subject’s legally authorized representitive is willing and able to provide informed consent, unless informed consent is not required (e.g., deceased subjects, as local regulations allow).

Exclusion Criteria

Subjects who meet ANY of the following criteria are not eligible for this study:

1. Subject has a known anaphylactic reaction to the active substance, to any of the excipients, or to hamster protein.
2. Subject has a concomitant bleeding disorder(s) other than AHA.
3. Subject has participated in another clinical study involving a medicinal

product or device within 30 days prior to enrollment or is scheduled to participate in another clinical study involving a medicinal product or device during the course of the study.

**Age groups**

- 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)

**Special population of interest**

Other

**Special population of interest, other**

Acquired hemophilia A patients

**Estimated number of subjects**

53

## Study design details

**Outcomes**

Incidence of therapy-related Serious Adverse Events (SAEs), Hemostatic effectiveness assessment for resolution of bleeding, Time to bleeding resolution, participant study termination, or switch to another treatment, Number of Obizur units/kg and infusions required for control of bleeding, Titer of anti-pFVIII inhibitors, Impact of inhibitor on hemostatic efficacy, Occurrence of hypersensitivity reactions, Occurrence of any thrombogenic event

**Data analysis plan**

SAEs will be described in listings and tables, and incidence rates will be calculated. Tables outlining the hemostatic effectiveness and immunogenicity of Obizur, frequency, total dose, and total number of infusions of Obizur required to control bleeding episodes will be developed.

## Documents

**Study results**

241302-clinical-study-report-redact.pdf (687.88 KB)

# 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**

Patient medical charts

## 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