# Cilostazol Drug Utilisation Study

**First published:** 04/03/2013

**Last updated:** 02/07/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS3596

**Study ID**

24988

**DARWIN EU® study**

No

**Study countries**

- ☐ Germany
- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom

**Study description**

Drug utilisation study (DUS) on the use of cilostazol in several European populations The DUS is a cohort study of new users of cilostazol. Five European population-based automated health databases are participating: Spain (IACS and SIDIAP), Germany (GePaRD--pending approvals), the United Kingdom (THIN), and Sweden (Swedish National Databases). The DUS is being conducted in two phases: DUS1 and DUS2. DUS1 has been completed and evaluated cilostazol as used in clinical practice in the target countries during the period from cilostazol launch through 2011. DUS2 will now be conducted after the implementation of changes to the summary of product characteristics (SmPC) and the follow-up communication activities with health care professionals (HCPs) and will evaluate the impact of these measures during the year 2014.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### RTI Health Solutions (RTI-HS)

- ☐ France
- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom
- ☐ United Kingdom (Northern Ireland)
- ☐ United States

**First published:** 21/04/2010

**Last updated:** 13/03/2025

Institution | Not-for-profit | ENCePP partner

## EpiChron Research Group on Chronic Diseases, Aragon Health Sciences Institute (IACS)

Spain

**First published:** 17/02/2017

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

Institution | Educational Institution | ENCePP partner

## Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

**First published:** 29/03/2010

**Last updated:** 26/02/2024

Institution | Not-for-profit | ENCePP partner

## Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

**First published:** 24/03/2010

**Last updated:** 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

## Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

**First published:** 05/10/2012

**Last updated:** 23/05/2025

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

# Contact details

**Study institution contact**

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Study contact

castellsague@rti.org

**Primary lead investigator**

Jordi Castellsague

Primary lead investigator

# Study timelines

**Date when funding contract was signed**
Actual: 15/01/2013

**Study start date**
Actual: 08/03/2013

**Data analysis start date**
Actual: 09/04/2013

**Date of interim report, if expected**
Actual: 31/03/2015

**Date of final study report**
Planned: 18/05/2017

Actual: 01/02/2017

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Otsuka Pharmaceutical Europe, Ltd.

# Study protocol

Cilostazol Protocol 2013Feb28.pdf(414.41 KB)

Cilostazol DUS2 Operational Protocol V02_05Nov2015.pdf(855.9 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)

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

**Main study objective:**

To describe: -the characteristics of new users of cilostazol according to 1)demographics, 2)baseline comorbidity including conditions listed in the SmPC

and the RMP as potential or identified safety concerns, 3)baseline and concurrent use of medications potentially interacting with cilostazol, and 4)specific comorbidity-the duration of the use of cilostazol and discontinuation patterns

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

CILOSTAZOL

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**Medical condition to be studied**

Intermittent claudication

## Population studied

**Short description of the study population**

All individuals registered in the study databases since the date of the first recorded prescription of cilostazol in each database

- The Aragón Health Sciences Institute (Instituto Aragonés de Ciencias de la Salud [IACS]) database, Spain
- The Information System for the Advancement of Research in Primary Care (Sistema d'Informació per el Desenvolupament de la Investigació en Atenció

Primària [SIDIAP]) database in Catalonia, Spain

- The German Pharmacoepidemiological Research Database (GePaRD ), Germany
- The Health Improvement Network (THIN), United Kingdom (UK)
- The Swedish National Databases.

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**Age groups**

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**

5600

## Study design details

**Outcomes**

patient characterization and prescription patterns

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**Data analysis plan**

The use and patterns of use of cilostazol will be summarized by the total number of users, prescriptions, and number of defined daily doses (DDDs), and by the number of users according to daily dose and duration of use. Characteristics of users, comorbidity, comedications, use of interacting drugs, and conditions defined for the evaluation of risk minimization measures, contraindications, indications, off-label use and prescriber speciality will be

described as number and percentage of patients with each condition. All analysis will be stratified by age and sex.

## Documents

**Study results**

Cilostazol DUS2_Final_Report_01Feb2017.pdf(3.31 MB)

**Study publications**

Castellsague J, Calingaert B, Poblador-Plou B, Giner-Soriano M, Linder M, Schol...

Castellsague J, Perez-Gutthann S, Calingaert B, Bui C, Varas-Lorenzo C, Arana A...

Jordi Castellsague J, Poblador-Plou B, Giner-Soriano M, Linder M, Scholle O, Ca...

# 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 source(s)**

THIN® (The Health Improvement Network®)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

The Information System for Research in Primary Care (SIDIAP)

German Pharmacoepidemiological Research Database

**Data source(s), other**

THIN, The Swedish prescribed drug register, SIDIAP, GePaRD

**Data sources (types)**

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

## 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**

Unknown