# Cilostazol Drug Utilisation Study

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

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





# Administrative details

**Study description** 

EU PAS number	
EUPAS3596	
Study ID	
24988	
DARWIN EU® study	
Study countries	
Germany	
Spain	
Sweden	
United Kingdom	

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.

# **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
<b>Last updated:</b> 13/03/2025

EpiChron Research Group on Chronic Diseases,
Aragon Health Sciences Institute (IACS)
Spain
First published: 17/02/2017
<b>Last updated:</b> 02/04/2024
Institution

# 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



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

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

#### 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

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

#### 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)

#### **Estimated number of subjects**

5600

# Study design details

#### **Outcomes**

patient characterization and prescription patterns

#### **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