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.

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: 11/08/2026

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: 30/03/2026

Institution | Not-for-profit | ENCePP partner

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 02/06/2026

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: 09/07/2026

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

Contact details

Study institution contact

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Study contact

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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

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.

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

5.600

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