Drug utilization study of mirabegron (Betmiga®) using real-world healthcare databases from the Netherlands, Spain, United Kingdom and Finland (Mirabegron DUS)

First published: 27/01/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS15063

Study ID

29595

DARWIN EU® study

No

Study countries

- [ ] Finland
- [ ] Netherlands

☐ Spain

☐ United Kingdom

Study description

The mirabegron (Betmiga®) Summary of Product Characteristics (SmPC) states that the drug is contraindicated in patients with “Severe uncontrolled hypertension defined as systolic blood pressure ≥180 mm Hg and/or diastolic blood pressure ≥110 mm Hg”. In accordance and compliance with the European Medicines Agencies (EMA’s) Pharmacovigilance Risk Assessment Committee (PRAC) request, a Direct Healthcare Professional Communication (DHPC) letter was disseminated on 7 September 2015 as a risk minimization activity in 30 countries in EU. In line with the EMA CHMP guideline Module IX, an effectiveness check of this risk minimization activity was proposed by Astellas. A drug utilization study (DUS) on the use of mirabegron in the Netherlands, Spain, United Kingdom and Finland will be performed as a risk minimization effectiveness check measure.The objectives of the study are to assess the effectiveness of the Direct Healthcare Professional Communication (DHPC) letter as a risk minimization measure in the participating countries by quantifying the proportions of mirabegron initiators with documented severe uncontrolled hypertension (primary objective) and the frequency of blood pressure recordings at baseline and during mirabegron treatment, especially in hypertensive patients (secondary objective) before and after DHPC dissemination.

Study status

Finalised

Research institutions and networks

Institutions

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

☐ Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution | Laboratory/Research/Testing facility | ENCePP partner

Clinical Practice Research Datalink (CPRD)

☐ United Kingdom

First published: 15/03/2010

Last updated: 17/01/2025

Institution | Laboratory/Research/Testing facility | ENCePP partner

Global Database Studies, IQVIA

☐ Czechia

☐ Finland

☐ Germany

☐ Slovakia

☐ Spain

First published: 17/01/2011

Last updated: 31/07/2024

Institution | Other | 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: 23/02/2024

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

Contact details

Study institution contact

Irene Bezemer pharmo@pharmo.nl

Study contact

pharmo@pharmo.nl

Primary lead investigator

Ron Herings

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/07/2016

Study start date
Actual: 21/02/2017

Data analysis start date
Actual: 17/03/2017

Date of final study report
Actual: 11/07/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas

Study protocol

178-pv-002-clp-en-final-v1-02.pdf(1.34 MB)

PHARMO-Study Protocol-Mirabegron DUS_v1.2.pdf(1.39 MB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The objectives are to assess the effectiveness of the DHPC letter as a risk minimization measure by quantifying the proportions of mirabegron initiators with severe uncontrolled hypertension (primary objective) and the frequency of blood pressure recordings at baseline and during mirabegron treatment, especially in hypertensive patients (secondary objective) before and after DHPC dissemination.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(G04BD12) mirabegron

mirabegron

Medical condition to be studied

Hypertension

Population studied

Short description of the study population

Mirabegron initiators during the years 2012-2016.

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)

Estimated number of subjects

50000

Study design details

Outcomes

For the primary objective we will assess whether the proportions of mirabegron initiators with documented hypertension (severe uncontrolled hypertension but also controlled hypertension or non-severe uncontrolled hypertension) differ

between the time periods before and after DHPC dissemination. For the secondary objective we will asses whether the frequency of blood pressure recordings at initiation and during mirabegron treatment among initiators with documented hypertension at index date differ between the time periods before and after DHPC dissemination.

Data analysis plan

The DHCP letter was disseminated on 7 September 2015. The analysis pre- and post dissemination will take this date as the intervention date. Besides a pre- and post dissemination analysis, incremental changes over time will be assessed using the aggregated data per quarter (January-March, April-June, July-September and October-December). To estimate incremental changes in response to the DHPC letter in the proportion of mirabegron initiators with normal blood pressure, controlled hypertension, non-severe uncontrolled hypertension and severe uncontrolled hypertension at index date (primary objective), an interrupted time series approach will be applied on the respective proportions in each quarter.The frequency of blood pressure recordings will be assessed before initiation of and during mirabegron treatment (see section 9.3.4). Blood pressure recordings at or before index date (up to 6 months) will be reported separately from the recordings during treatment.

Documents

Study results

178-pv-002-clgr-disc01-en-final-04.pdf(111.31 KB)

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

The Information System for Research in Primary Care (SIDIAP)

PHARMO Data Network

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

The Finnish data sources include the e-Prescription Register, Care Register for Health Care, Register of Primary Health Care Visits, Population Register Centre and Causes of Death Registry of Finland and electronic medical record databases of city of Helsinki, Vantaa and Espoo.

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