Safety Evaluation of Adverse Reactions in Diabetes - Drug utilisation studies (SAFEGUARD)

First published: 22/08/2013

Last updated: 31/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20761

EU PAS number

EUPAS4364

Study ID

20761

DARWIN EU® study

No

Study countries

☐ Germany

- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom
- [ ] United States

Study description

The safety of pharmacological treatments used in type 2 diabetes is an ongoing concern. Associations between drugs such as rosiglitazone, pioglitazone and exenatide and adverse cardiovascular, urinary and pancreatic health outcomes have all been suggested in the last decade. Assessments of these associations have been complicated by the complex, often heterogeneous nature of type 2 diabetes treatment and by the strong link between severity of diabetes and/or non-response to treatment and changes in treatment. In a number of countries, information on both prescribing and/or dispensing of these medications and the adverse health outcomes potentially associated with them is routinely collected in electronic healthcare databases. Work package 4 of the FP7 funded Safety Evaluation of Adverse Reactions in Diabetes (SAFEGUARD) project seeks to utilize such databases to assess the safety of type 2 diabetes treatments. The primary objective of the SAFEGUARD Drug Utilisation Study (DUS) is to describe the use of non-insulin blood glucose lowering agents, insulin and insulin analogues in the data sources involved in SAFEGUARD. Utilisation will be described at a population, patient and prescription level and results will be presented stratified across a range of patient characteristics and other covariates. The results will provide information on the utilisation of type 2 diabetes drugs across six countries and will be used to inform exposure assessment and control of confounding in SAFEGUARD studies assessing the safety of drugs used in type 2 diabetes.

Study status

Finalised

Research institutions and networks

Institutions

Erasmus Medical Centre Rotterdam

First published: 01/02/2024

Last updated: 01/02/2024

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

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

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

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

- [ ] Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

Società Italiana di Medicina Generale e delle Cure Primarie (SIMG)

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Patient organisation/association

University of Bath

First published: 01/02/2024

Last updated: 01/02/2024

Institution

AEMPS Spain, UNIMIB Italy, BWH United States of America

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Miriam Sturkenboom

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 23/08/2011

Actual: 23/08/2013

Study start date
Planned: 26/07/2013

Actual: 26/07/2013

Data analysis start date
Planned: 01/09/2013

Actual: 05/09/2013

Date of final study report
Planned: 30/09/2015

Actual: 25/08/2017

Sources of funding

- EU institutional research programme

More details on funding

Health Area of the European Commission under the VII Framework Programme

Study protocol

Safety Evaluation of Adverse Reactions In Diabetes - Drug Utilisation Study.pdf

(547.67 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

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 use of non-insulin blood glucose lowering drugs (NIBGLD), insulins and insulin analogues at a population, patient and prescription level.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive retrospective observational study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10) DRUGS USED IN DIABETES

DRUGS USED IN DIABETES

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

All patients (not just those diagnosed with T2DM) mellitus in the databases during the study period who have at least 365 consecutive days of valid data.

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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)

Special population of interest

Other

Special population of interest, other

Diabetes mellitus patients

Estimated number of subjects

50000000

Study design details

Data analysis plan

The monthly incidence, prevalence and volume of exposure to different A10* coded drugs, drug classes and treatment regimens will be described. Rates of initiation, discontinuation and switching of each treatment will be calculated and patient characteristics associated with each rate will be described. Statistics describing the typical number, duration and dose of treatment episodes with each drug, drug class or treatment regimen per patient will be described. All results will be compared across age, sex and calendar year as well as across each of the participating data sources.

Documents

Study results

Executive Summary_DUS_19APR2016.pdf(202.14 KB)

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

DoI_MS_ENCePP_SDPP_4364.pdf(197.66 KB)

Composition of steering group and observers

ENCEPP_SDPP_4364_Scientific Advisory Board.pdf(77.91 KB)

Signed code of conduct

4364_Declaration of Compliance_signed.pdf(315.37 KB)

Signed code of conduct checklist

4364_Code of Conduct Checklist_signed.pdf(899.03 KB)

Signed checklist for study protocols

4364_Checklist for Study Protocols_signed.pdf(1.41 MB)

Data sources

Data source(s)

Clinical Practice Research Datalink

Health Search/IQVIA Health Longitudinal Patient Database

Integrated Primary Care Information (IPCI)

PHARMO Data Network

Data source(s), other

CPRD, Health Search/CSD LPD, IPCI, PHARMO Data Network

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