DARWIN EU® – Paracetamol prescribing and paracetamol overdose in Europe: a descriptive analysis of trends and patient characteristics

First published: 04/10/2024

Last updated: 03/03/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000329

EU PAS number

EUPAS1000000329

Study ID

1000000329

DARWIN EU® study

Yes

Study countries

- [ ] Croatia
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Portugal
- [ ] Spain
- [ ] United Kingdom

Study description

Paracetamol (acetaminophen) is one of the most widely used medicines worldwide and is available over the counter in the European Union. It is one of the most common causes of drug poisonings and can result in severe hepatic failure. Different regulatory interventions at national level have occurred to reduce the incidence of paracetamol overdose, but it is uncertain how paracetamol is prescribed across Europe and to what extent prescription may be involved in poisonings.

Research question and objectives

The aim of the study is to provide an overview of paracetamol prescribing and paracetamol overdose trends in selected European databases, and to characterise patients presenting with paracetamol overdose.

The specific objectives of the study are:

1. To examine the incidence/prevalence of paracetamol prescribing (overall, and by age, sex, formulation and country/database).
2. To examine the incidence of paracetamol overdose (overall, and by age, sex, country/database).
3. To characterise patients with paracetamol overdose, in terms of comorbidities, co-prescribed medications, prior paracetamol prescription, and

incidence of short-term complications and mortality.

Study status

Finalised

Research institutions and networks

Institutions

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**

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

☐ Belgium
☐ Croatia
☐ Denmark
☐ Estonia
☐ Finland
☐ France

- [ ] Germany
- [ ] Hungary
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] United Kingdom

First published: 01/02/2024

Last updated: 11/06/2024

Network

Contact details

Study institution contact

Ilse Schuemie

Study contact

study@darwin-eu.org

Primary lead investigator

Berta Raventos

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/07/2024

Actual: 24/07/2024

Study start date
Planned: 12/09/2024

Actual: 12/09/2024

Date of final study report
Planned: 07/02/2025

Actual: 06/02/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P3-C1-007_Paracetamol_V2.pdf(724.56 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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

1. Population-level drug utilisation study to assess incidence and prevalence of paracetamol prescribing (objective 1) 2. Population-level descriptive epidemiology study to estimate the incidence of paracetamol overdose (objective 2)
3. Patient-level characterisation study

Main study objective:

The aim of the study is to provide an overview of paracetamol prescribing and paracetamol overdose trends in selected European databases, and to characterise patients presenting with paracetamol overdose.

The specific objectives of the study are:
1. To examine the incidence/prevalence of paracetamol prescribing (overall, and by age, sex, formulation and country/database).
2. To examine the incidence of paracetamol overdose (overall, and by age, sex, country/database).
3. To characterise patients with paracetamol overdose, in terms of

comorbidities, co-prescribed medications, prior paracetamol prescription, and incidence of short-term complications and mortality.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

PARACETAMOL

Anatomical Therapeutic Chemical (ATC) code

(N02BE01) paracetamol

paracetamol

Population studied

Short description of the study population

For objective 1 and 2, the study population will comprise all individuals present in the database at any time from 1st January 2010 to 31st of December 2023 (or the latest year with complete observation). For objective 3, the study will comprise of individuals with paracetamol overdose for the first time in their patient history during the study period.

For incidence calculations (objective 1 and 2), individuals with a record of the outcome will re-enter the study after a certain amount of time (i.e. washout

period) so further occurrences of the outcome can be captured. This washout period will be defined as 60 days following the end of the prescribed treatment for paracetamol prescribing and 365 days for paracetamol overdose. For objective 3, individuals with a prior history of paracetamol overdose any time prior to index date will be excluded.

A year of observation history prior to index date will be required for all individuals within selected databases except CDWBordeaux. Individuals aged less than 1 year of observation history will be excluded.

Study design details

Setting

This study will be conducted using routinely collected data from 8 databases in 7 European countries selected from the DARWIN EU® Database Catalogue. All databases were previously mapped to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM).

Documents

Study report

DARWIN EU_Report_P3-C1-007_Paracetamol_V2.pdf(2.73 MB)

Data management

Data sources

Data source(s)

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

Clinical Practice Research Datalink (CPRD) GOLD

Danish Health Data Registries

IQVIA Disease Analyzer Germany

UK Biobank

Clinical Data Warehouse of the Bordeaux University Hospital

Egas Moniz Database

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown