DARWIN EU® Comparing direct and indirect methods to estimate prevalence of chronic diseases using real-world data

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Administrative details

EU PAS number

EUPAS100000088

Study ID

100000088

DARWIN EU® study

Yes

Study countries

Netherlands

Spain

United Kingdom

Study description

In the context of chronic diseases with relatively low prevalence, how do direct and indirect RWD-based estimates of prevalence compare with each other?

The specific objectives of this study are to:

1) Estimate the disease prevalence (direct estimate based on the proportion of individuals with the condition).

2) Estimate the disease incidence rate.

3) Estimate duration of disease using Kaplan-Meier survival curves. Of particular interest is the estimate of median survival as a summary measure of disease duration.

4) Produce an indirect estimation of prevalence as the product of incidence and median survival.

for the following diseases:

- Cystic fibrosis
- Haemophilia (A and/or B)
- Pulmonary arterial hypertension
- Pancreatic cancer
- Sickle cell disease

Results will be provided overall and where possible stratified by age group: paediatrics (0-17 years old) and adults (18 years old and above).

Study status

Finalised

Research institutions and networks

Networks

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

Belgium

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Croatia

Denmark

- Estonia
- Finland
- France

Germany

Greece

Hungary

Italy

Netherlands

Norway

___ Portugal

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Sweden

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Contact details

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Primary lead investigator

Study timelines

Date when funding contract was signed Planned: 12/12/2023 Actual: 12/12/2023

Study start date Planned: 01/01/2010 Actual: 01/01/2010

Date of final study report Planned: 22/04/2024 Actual: 26/06/2024

Sources of funding

• EMA

Study protocol

DARWIN EU_D2.2.3_Protocol_P2-C1-013_Direct and indirect prevalence estimation V2.pdf(659 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

Study type:

Non-interventional study

Study design:

A retrospective cohort design to estimate disease point prevalence and incidence. A retrospective cohort design to estimate median survival as a proxy for disease duration. Data from three databases with routinely-collected electronic healthcare records of general practices will be used.

Main study objective:

The objective of this study is to compare direct and indirect estimations of prevalence of some rare, chronic diseases.

Study drug and medical condition

Medical condition to be studied

Cystic fibrosis Haemophilia Pulmonary arterial hypertension Pancreatic carcinoma Sickle cell disease

Population studied

Age groups

Paediatric Population (< 18 years) Preterm newborn infants (0 – 27 days) Term newborn infants (0 – 27 days) Infants and toddlers (28 days – 23 months) Children (2 to < 12 years) Adolescents (12 to < 18 years) Adult and elderly population (\geq 18 years) Adults (18 to < 65 years) Adults (18 to < 46 years) Adults (46 to < 65 years) Elderly (\geq 65 years) Adults (65 to < 75 years) Adults (75 to < 85 years) Adults (85 years and over)

Documents

Study report

DARWIN EU_D2.2.4_Report_P2-C1-013_IndirectPrevalence_V3.pdf(952.36 KB)

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink (CPRD) GOLD Integrated Primary Care Information (IPCI) The Information System for Research in Primary Care (SIDIAP)

Use of a Common Data Model (CDM)

CDM mapping Yes

CDM Mappings

CDM name

OMOP

CDM website

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

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No