DARWIN EU® – Frailty and polypharmacy among adults with selected cancers at the time of diagnosis

First published: 22/04/2024

Last updated: 11/11/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000120

EU PAS number

EUPAS1000000120

Study ID

1000000120

DARWIN EU® study

Yes

Study countries

☐ Belgium

- [ ] Estonia
- [ ] Germany
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

Study description

This study intends to investigate the ability to characterise frailty and polypharmacy in real-world data sources, to estimate the prevalence of frailty and polypharmacy in people aged 18 and above with selected cancers at the point of diagnosis and to describe their characteristics. While the focus is on older adults, the study will explore the full age range of adulthood to better contextualise the results.

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

IQVIA NL, Real-World-Evidence

Netherlands

First published: 25/11/2022

Last updated: 21/03/2025

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

University of Oxford, University of Tartu

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

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Study contact

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Primary lead investigator

Talita Duarte-Salles

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 19/04/2024

Study start date
Planned: 05/04/2024

Date of final study report
Planned: 31/05/2024

Actual: 09/07/2024

Sources of funding

- EMA

Study protocol

DARWIN_EU_D2.2.3_Protocol_P2-C1-009_Frailty and Polypharmacy at cancer diagnosis_v2.3.pdf(1.58 MB)

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 type:

Non-interventional study

Study design:

A population-based cohort study of all incident cases of selected cancers will be conducted.

Main study objective:

The aim of this study is to estimate the prevalence of frailty and polypharmacy at the point of diagnosis of selected cancers in adults and to describe their characteristics.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Breast cancer

Ovarian cancer

Endometrial cancer

Prostate cancer

Colorectal cancer

Lymphoma

Additional medical condition(s)

Lung cancer, pancreatic cancer, leukemia and myeloma

Population studied

Short description of the study population

The study population will include all individuals aged 18 years and above with a primary diagnosis of selected cancers (lung, breast, ovary, endometrium, prostate, pancreas, colorectal cancer, lymphoma, leukemia and myeloma) recorded between 01/01/2017 and 31/12/2022, with at least one year of prior history available before cancer diagnosis. Individuals with a diagnosis of cancer (any, excluding non-melanoma skin cancer) any time prior to the diagnosis of one of the selected cancers will be excluded.

Additional eligibility of a minimum of 1 year of potential follow-up time prior to the end of last database observations will be imposed for the estimation of one-year hospitalisation and mortality rates if the data sources capture this information.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Study design details

Setting

This study will be conducted using routinely collected health data from 6 databases in the DARWIN EU network of data partners from 6 European countries. All databases were previously mapped to the OMOP CDM.

Data sources

1. Clinical Practice Research Datalink (CPRD) GOLD, United Kingdom
2. IQVIA Disease Analyzer Germany (IQVIA DA Germany), Germany
3. IQVIA Longitudinal Patient Database Belgium (IQVIA LPD Belgium), Belgium
4. Integrated Primary Care Information Project (IPCI), The Netherlands
5. Estonian Biobank (EBB), Estonia
6. Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària (SIDIAP), Spain

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Data analysis plan

Population-level descriptive epidemiology:

- Prevalence rates of the condition of interest

Patient-level characterisation:

- Large-scale characterisation
- Patient-level characteristics
- Prognosis / progression to a pre-specified outcome

Documents

Study report

DARWIN EU_D2.2.4_Report_P2-C1-009 Frailty and polypharmacy report_V4.pdf

(5.9 MB)

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink (CPRD) GOLD

Estonian Biobank

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

IQVIA Disease Analyzer Germany

IQVIA Longitudinal Patient Data - Belgium

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

Unknown