DARWIN EU® - Treatment characterisation and post-diagnosis outcomes in Alzheimer’s disease

First published: 10/11/2025

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Study Planned

Administrative details

EU PAS number

EUPAS1000000827

Study ID

1000000827

DARWIN EU® study

Yes

Study countries

- [ ] Croatia
- [ ] Denmark
- [ ] Germany
- [ ] Netherlands

Study description

Alzheimer’s disease (AD) is the most common cause of dementia, characterised by progressive cognitive
decline and increasing loss of independence. Its burden is rising globally due to population ageing, with
substantial implications for healthcare systems and society. Recent therapeutic advances, such as the
approval of anti-amyloid monoclonal antibodies, are reshaping AD management, but also highlight the
need for updated real-world evidence on the epidemiology and characteristics of affected populations.

Study status

Planned

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
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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Last updated: 30/04/2025

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Melissa Leung

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/09/2025

Actual: 08/09/2025

Study start date

Planned: 28/11/2025

Date of final study report

Planned: 27/03/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C1-023_Alzheimer's - post-diagnosis outcomes _V5.0.pdf (1.13 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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

This study will be conducted using routinely collected data from five primary/secondary care data sources
in the DARWIN EU® network of data partners from four European countries

Main study objective:

Objective 1. To characterise treatments received by individuals newly diagnosed with Alzheimer’s disease, in the year, three, and five years following diagnosis.

Objective 2. To describe the timing and frequency of relevant clinical and care-related events following Alzheimer’s disease diagnosis, including (when available):

Hospitalisations at fixed time points (e.g., 1-, 3-, and 5-years post-diagnosis)

Healthcare system utilisation (number of outpatient visits at 1-, 3-, and 5-years post-diagnosis)

Time to first record of caregiver support

Time to nursing home or hospice admission

Death at fixed time points (e.g., 1-, 3-, and 5-years post-diagnosis)

Objective 3. To describe time to death from first initiation of treatment following Alzheimer’s disease diagnosis

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Dementia Alzheimer's type

Population studied

Short description of the study population

The study population for objectives 1 and 5b will include individuals with incident AD and with AD
treatment initiation between 01/01/2014 and 31/12/2023.The study population for objectives 2, 3b, 4a–b,
4d, and 5a will include individuals in the data source with incident AD, defined as a first diagnosis of AD
between 01/01/2014 and 31/12/2023 with at least 365 days of database history prior to the date of the
first diagnosis of AD (index date) and aged ≥18 years at index date. The study population for objective 3a
will include individuals with incident AD between 01/01/2014 and 31/12/2023 and no history of AD
treatment prior to the first diagnosis of AD. The study population for objective 4c will include individuals
with incident AD between 01/01/2014 and 31/12/2023 and no history of caregiver support prior to the first
diagnosis of AD.

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

Outcomes

prescription of a pharmacological treatments for AD (objectives 2 and 3), occurrence of clinical and care-related events (objective 4), and survival (objective 5). The pharmacological treatments of interest are acetylcholinesterase inhibitors (donepezil, rivastigmine, and galantamine), memantine, and antipsychotics. The clinical and care-related events of interest are hospitalisation, outpatient visit, and caregiver support.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

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

Danish Health Data Registries

InGef Research Database

IQVIA Disease Analyzer Germany

Integrated Primary Care Information (IPCI)

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

No