DARWIN EU® - Feasibility of studies on early (pre-symptomatic) stages of type 1 diabetes mellitus in the DARWIN EU® network

First published: 24/09/2025

Last updated: 25/09/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000756

Study ID

1000000756

DARWIN EU® study

Yes

Study countries

- [ ] Denmark
- [ ] Finland
- [ ] France

- [ ] Hungary
- [ ] Netherlands
- [ ] Spain

Study description

Identifying type 1 diabetes mellitus at an early, presymptomatic stage offers clinical advantages. These benefits include a decreased risk of diabetic ketoacidosis (DKA) at the onset of the disease and a notable reduction in clinical symptoms. Additionally, products such as Tzield (teplizumab) are being developed to target early stages of type 1 diabetes mellitus, aiming to delay disease progression. There is also increasing attention in clinical practice to early screening (via specific antibodies), which helps in identifying candidates for disease-modifying therapies and provides early access to diabetes-related education and disease management.

Study status

Ongoing

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

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

Natasha Yefimenko study@darwin-eu.org

Study contact

study@darwin-eu.org

Primary lead investigator

Julieta Politi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/04/2025

Actual: 15/04/2025

Study start date

Planned: 11/08/2025

Actual: 11/08/2025

Date of final study report

Planned: 31/12/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C1-010_Feasibility of DMT1 studies_V3.0.pdf (951.88 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 topic, other:

Type 1 Diabetes mellitus

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 6 data sources, including primary care (n=1), hospital care (n=4), and registry-based data settings (n=1) within the DARWIN EU® network of data partners, and from 6 EU member states. All data were a priori mapped to the OMOP CDM.

Main study objective:

The aim of this study is to investigate the feasibility of conducting research on the early (pre-symptomatic) stages of type 1 diabetes mellitus within the DARWIN EU® network. It will focus on the frequency and timing of autoantibody and glucose testing before the disease becomes clinically apparent.

The specific objectives for this study are:

1. To describe the characteristics of individuals newly diagnosed with type 1 diabetes mellitus in terms of demographics, prespecified comorbidities and medications, and diagnostic tests of interest (HbA1C, C-peptide, glucose, and each autoantibody assay), prior to and at the time of type 1 diabetes mellitus diagnosis, and to assess selected characteristics at one-year post-diagnosis.
2. To estimate, for each diagnostic test of interest (HbA1C, C-peptide, glucose, and each autoantibody assay), the median (IQR) time in days from 1) the earliest recorded test and 2) the earliest recorded abnormal result (where ascertainable) to the date of first-ever type 1 diabetes mellitus diagnosis.
3. To estimate the annual point prevalence of type 1 diabetes mellitus during 2015–2024, using population-based data sources.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

Objectives 1 and 2 (newly diagnosed type 1 diabetes mellitus cohort):

Inclusion criteria

First-ever recorded diagnosis of type 1 diabetes mellitus during the study period.

Objective 3:

Inclusion criteria

• All individuals present in the period from 01/01/2015 to 31/12/2024 (or the first and latest available date)

• Minimum 365 days of available history before the index date (applied to non-hospital-based data sources and individuals aged 1 year or older).

Age groups

All

In utero

Paediatric Population (< 18 years)

Neonate

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 (≥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)

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)

Danish Health Care Registries

TaUH patient cohort (FinOMOP)

Clinical Data Warehouse of the Bordeaux University Hospital

Semmelweis University Clinical Data

Integrated Primary Care Information (IPCI)

Data source(s), other

Hospital Universitario 12 de Octubre

Data sources (types)

Electronic healthcare records (EHR)

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