DARWIN EU® - Characteristics of individuals with acute graft vs. host disease with intestinal involvement

First published: 17/12/2025

Last updated: 11/03/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000878

Study ID

1000000878

DARWIN EU® study

Yes

Study countries

- [ ] France
- [ ] Germany
- [ ] Spain

Study description

Acute graft-versus-host disease (aGvHD) is a serious and potentially life-threatening complication that can
occur after allogeneic hematopoietic stem cell transplantation (allo-HSCT). Intestinal involvement in aGvHD is particularly severe and is associated with poor prognosis. This form of
aGvHD is often resistant to first-line corticosteroid therapy, and failure of second-line treatments like
ruxolitinib further complicates management and has a poor prognosis.
Given the high mortality associated with advanced gastrointestinal (GI) aGvHD, especially after failure of
standard treatments, there is a need to generate data on use of treatment for aGvHD with intestinal
involvement in real life.

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

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Katia Verhamme

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/10/2025

Actual: 30/10/2025

Study start date

Planned: 11/12/2025

Actual: 11/12/2025

Date of final study report

Planned: 27/03/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C1-019_GvHD intestinal_V4.0.pdf (930.07 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

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

A cohort study will be conducted using routinely collected health data from 3 data sources from 3 countries across Europe.

Main study objective:

1. Describe the baseline characteristics (age, sex, transplant type, indication of transplant, treatment (corticosteroids, ruxolitinib, and other second line treatment for aGvHD), and mortality) of patients with aGvHD.
2. Describe the baseline characteristics (age, sex, transplant type, indication of transplant, treatment (corticosteroids, ruxolitinib, and other second line treatment for aGvHD), and mortality) of patients with aGvHD with intestinal involvement.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Acute graft versus host disease

Acute graft versus host disease in intestine

Population studied

Short description of the study population

Inclusion criteria:

For objective 1, the study population will consist of all individuals with at least 365 days of database history, a diagnosis with aGvHD or aGvHD with intestinal involvement, and with a minimum age of 18 years at time of diagnosis.

Exclusion criteria:

• Individuals with a history of aGvHD prior to the start of the study period

• Less than 365 days of database history prior to the index date

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Age groups

- **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)

Study design details

Outcomes

Mortality will be assessed in three time windows following index date, both in the aGvHD and aGvHD with

intestinal involvement cohort (irrespective of treatment)

These windows are:

o In the window from index date (day 0) to 30 days following index date

o In the window from 31 days up to 90 days following index date

o In the window from 91 to 365 days following index date

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)

The Valencia Health System Integrated Database

InGef Research Database

IATROS

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