

DARWIN EU® - Real-World Overall Survival in Patients with Acute Gut GvHD Following Failure of Corticosteroids and Ruxolitinib

First published: 16/07/2026

Last updated: 20/08/2026

Study

Ongoing

Administrative details

EU PAS number

EUPAS1000001062

Study ID

1000001062

DARWIN EU® study

Yes

Study countries

 Belgium

 Denmark

 Germany

 Spain

Study description

Acute graft-versus-host disease (aGvHD) is a serious complication of allogeneic haematopoietic stem cell transplantation (allo-HSCT). Intestinal involvement is associated with severe disease, poor prognosis, and frequent resistance to first-line corticosteroid therapy. Failure of second-line treatments with ruxolitinib further limits therapeutic options and is associated with poor outcomes. However, evidence on treatment patterns and survival in routine clinical practice, particularly following failure of corticosteroids and ruxolitinib, remains limited. This study aims to generate real-world evidence on treatment use and survival outcomes among patients with aGvHD with intestinal involvement.

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

Marzyeh Amini

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/03/2026

Actual: 05/03/2026

Study start date

Planned: 18/06/2026

Actual: 18/06/2026

Date of final study report

Planned: 22/12/2026

Sources of funding

- EMA

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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

A retrospective cohort study will be conducted using routinely collected health data from five data sources.

Main study objective:

intestinal involvement, including age, sex, transplant type, and indication for transplant.

2. To describe treatment duration of individual treatments, progression to subsequent treatment lines, and the time from aGvHD diagnosis to initiation of second- and third-line therapy among patients with aGvHD with intestinal involvement.

3. To evaluate rwPFS in patients who initiate third-line therapy after failure of corticosteroids and ruxolitinib.

4. To evaluate overall survival up to one year in patients who initiate third-line therapy after failure of corticosteroids and ruxolitinib.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Ruxolitinib

Medical condition to be studied

Acute graft versus host disease in intestine

Population studied

Short description of the study population

The phenotype of aGvHD with intestinal involvement will consist of patients with a disease code for Graft versus host disease of intestine. If source data are not sufficiently granular, the phenotype will be defined as the presence of Acute graft versus host disease in combination with intestinal symptoms recorded during the same visit occurrence or within -14/+14 days of the index date. Intestinal symptoms include gastrointestinal haemorrhage, abdominal pain and tenderness, abdominal distension/bloating, diarrhoea, haematochezia, nausea, vomiting, anorectal tenesmus, malabsorption syndrome, loss or decrease of appetite, intestinal disorders and inflammatory digestive tract disorders, enterocolitis-related conditions, paralytic ileus, nutritional complications (e.g. protein-calorie malnutrition), dyspepsia, changes in stool output, and evidence of gastrointestinal endoscopy or biopsy

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)

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)

University Hospital Antwerp structured data

Danish Health Data Registries

InGef Research Database

The Valencia Health System Integrated Database

IQVIA US PharMetrics® Plus

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/cdm54.html>

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No