Assessment of the Association of Progression to High-Risk Varices With Death and Liver Transplantation Rates in Patients With Compensated Cirrhosis

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000001061

Study ID

1000001061

DARWIN EU® study

Yes

Study countries

Sweden

Study description

The study will assess the occurrence of liver transplantation and death in patients with compensated cirrhosis (any etiology) who experience clinically significant events relating to liver decompensation.

Study status

Ongoing

Research institutions and networks

Institutions

F. Hoffmann-La Roche

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Institution

Quantify Research AB

Contact details

Study institution contact

Ashwini Shewade global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Emilie Toresson Grip

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 10/12/2025

Study start date
Actual: 12/12/2025

Data analysis start date
Actual: 18/06/2026

Date of interim report, if expected
Planned: 20/07/2026

Date of final study report
Planned: 30/09/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F. Hoffmann-La Roche Ltd.

Study protocol

SG46805_-_PEGOZAFERMIN_-_v1.1_FINAL_Redacted.pdf (2.27 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

SG46805

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Hypothesis generation (including signal detection)

Data collection methods:

Secondary use of data

Study design:

An observational cohort study utilizing data from 2005-2022 in Swedish national and regional (Stockholm regional electronic health records [EHRs]) registers. The study will conduct secondary data analysis via the Health Outcomes and Risk Assessment in Chronic Liver Disease (HERALD) platform.

Main study objective:

The main objective of this study is to identify and characterize patients with compensated cirrhosis (any etiology) belonging to study cohorts defined based on earliest protocol defined event, along with estimating the risk of liver transplantation and all-cause, cardiovascular-specific, and liver-specific mortality from the index date in patients across all cohorts.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Metabolic dysfunction-associated steatohepatitis

Hepatic cirrhosis

Additional medical condition(s)

Liver decompensation

Population studied

Short description of the study population

Adults with compensated cirrhosis without a previous history of protocol-defined events

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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)

Estimated number of subjects

58197

Study design details

Setting

- Swedish National Cohort:
- Patient has at least one (≥1) primary or secondary diagnosis of compensated cirrhosis recorded in the national in- or outpatient secondary care registers or in the regional EHRs during the inclusion period between 01 January 2006 and 01 November 2021 (National population)
- Patient has a first occurrence of any of the protocol defined events during the inclusion period
- Stockholm Cohort:
- Patient has at least one (≥1) primary or secondary diagnosis of compensated cirrhosis recorded in the national in- or outpatient secondary care registers or in the regional EHRs during the inclusion period between 1 January 2011 and 26 October 2020
- Patient has a first occurrence of any of the protocol defined events during the inclusion period
- Patient has at least one observation in the TakeCare EHR data

Exclusion Criteria:

- Patient has evidence of decompensated cirrhosis prior to their first protocol defined event

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Outcomes

• Liver transplantation
• All-cause mortality
• Cardiovascular-related mortality
• Liver-related mortality

Data analysis plan

Descriptive statistics will be generated to summarize patient characteristics. Continuous covariates will be described by mean, standard deviation (SD), and interquartile range (IQR). Categorical covariates will be described by proportion and frequency in each category.

For Time-to-event analyses: Counts (proportions) and cumulative incidence and 95% confidence interval (CI) stratified by cohort and subcohort at 1-, 3-, 5-years post-index and overall will be described. Median time to survival and 95% CI by cohort and subcohort; cumulative incidence plots by cohort and subcohort; unadjusted and adjusted hazard ratios (95% CI) for study cohorts defined based on protocol defined events will be generated.

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 sources (types)

Electronic healthcare records (EHR)

Population registry

Use of a Common Data Model (CDM)

CDM mapping

Yes

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction

Data characterisation details

The Swedish national health care registries offer high quality data for research with nation-wide coverage and close to complete data for most available variables. Patient-level data from each register is available for research upon

prior ethics approval and individual patients can be linked between all data sets via the personal identifier given to all Swedish citizens. The national health care registries to be used in this study are the NPR, PDR, CDR, and LISA.
Regional data for the Stockholm population has been extracted from the primary and specialist care EHR system named TakeCare, and data from the FibroScan (VCTE) machine at the Hepatology clinic at Karolinska University hospital in Huddinge, Stockholm.