

WEUSKOP7134: A prospective, observational cohort study nested within the HCV Research UK National Registry to evaluate real-world use of eltrombopag in adult patients with chronic Hepatitis C Virus infection who are unable to initiate or maintain optimal interferon-based therapy due to thrombocytopenia (201109)

**First published:** 22/08/2014

**Last updated:** 29/03/2024

Study

Finalised

## Administrative details

**EU PAS number**

EUPAS7305

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**Study ID**

17398


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**DARWIN EU® study**

No

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### **Study countries**

 United Kingdom

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### **Study description**

Eltrombopag is a 2nd generation oral thrombopoietin receptor agonist developed by GlaxoSmithKline (GSK) and approved for the treatment of chronic immune (idiopathic) thrombocytopenia (ITP) and hepatitis C associated thrombocytopenia. The aim of this study is to report the incidence of hepatic decompensation among eltrombopag user with chronic hepatitis C virus infection who are unable to initiate or maintain optimal interferon-based therapy due to thrombocytopenia. This study is a multi-center, prospective, observational study nested within the HCV Research UK study, and conducted to evaluate patients treated with eltrombopag. Patients will be followed for a period of up to 3 years after initiating eltrombopag, based on routine care, patients will be assessed regularly during interferon-based therapy and thereafter according to local standard practice.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

[University of Glasgow](#)

Multiple centres: 40 centers are involved in the study

## Contact details

### Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

[Pharma.CDR@gsk.com](mailto:Pharma.CDR@gsk.com)

### Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 31/10/2013

Actual: 31/10/2013

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### Study start date

Planned: 31/10/2014

Actual: 12/08/2014

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## Date of final study report

Planned: 31/12/2018

Actual: 25/06/2015

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## Study protocol

[Epi-Prot-WEUSKOP7134-protocol-redact.pdf](#) (882.38 KB)

## Regulatory

### Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition  
Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness  
Disease epidemiology  
Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The aim of this study is to report the incidence of hepatic decompensation among eltrombopag users with chronic hepatitis C virus infection who are unable to initiate or maintain optimal interferon-based therapy due to thrombocytopenia.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

## **Study drug International non-proprietary name (INN) or common name**

ELTROMBOPAG

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## **Medical condition to be studied**

Hepatitis C

## Population studied

### **Short description of the study population**

Hepatitis C virus-infected patients treated with eltrombopag who were unable to initiate or maintain optimal interferon-based therapy due to thrombocytopenia.

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### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Special population of interest**

Hepatic impaired

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### **Estimated number of subjects**

200

## Study design details

## Outcomes

The aim of this study is to report the incidence of hepatic decompensation among eltrombopag users with chronic hepatitis C virus infection who are unable to initiate or maintain optimal interferon-based therapy due to thrombocytopenia. Secondary objectives include reporting incidence of thromboembolic events and mortality and identifying risk factors for hepatic decompensation, thromboembolic events and mortality among eltrombopag users in a real-world setting. The study will also report the 3- year incidence of hepatic decompensation and mortality and examine effectiveness of eltrombopag to initiate and maintain HCV therapy.

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## Data analysis plan

Cumulative incidence rates and corresponding 95% confidence intervals as well as Kaplan-Meier rates and corresponding 95% confidence intervals will be calculated for the occurrence of hepatic decompensation, thromboembolic events, or mortality, as separate events, at multiple time points during and at the end of the 3-year followup period. Cumulative incidence rates and corresponding 95% confidence intervals as well as Kaplan-Meier rates and corresponding 95% confidence intervals will be calculated for the occurrence of hepatic decompensation, thromboembolic events, or mortality, as separate events, at multiple time points during and at the end of the 3-year followup period.

## Documents

### Study results

[gsk-201109-clinical-study-result-summary.pdf](#) (127.15 KB)

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## 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)

[Disease registry](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

## **Data characterisation conducted**

Unknown