Post-Marketing Requirement study to evaluate the safety of octaplas™ versus plasma in patients undergoing orthotopic liver transplantation with special emphasis on hyperfibrinolysis

First published: 22/01/2016

Last updated: 16/03/2020

Study | Finalised

Administrative details

EU PAS number

EUPAS12164

Study ID

34140

DARWIN EU® study

No

Study countries

United States

Study description

This trial was terminated early after FDA released the requirements to conduct the trial. No meaningful results could be obtained based on the limited data obtained.

Study status

Finalised

Research institutions and networks

Institutions

Octapharma

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 5 centres are involved in the study

Contact details

Study institution contact

Michael Eppolito michael.eppolito@octapharma.com

Study contact

michael.eppolito@octapharma.com

Primary lead investigator

Michael Eppolito

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/06/2015

Study start date

Actual: 16/11/2015

Date of final study report

Planned: 16/01/2020

Actual: 11/02/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Octapharma U.S.A. Inc.

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

To assess the incidence of hyperfibrinolysis

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To assess the incidence of hyperfibrinolysis in patients undergoing orthotopic liver transplant (OLT) receiving octaplas™ in comparison to those receiving plasma issued according to institutional standard of care

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-Marketing Requirement study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B05AA) Blood substitutes and plasma protein fractions

Blood substitutes and plasma protein fractions

Medical condition to be studied

Liver transplant

Population studied

Short description of the study population

Patients undergoing orthotopic liver transplant (OLT) receiving octaplas™ or plasma issued according to institutional standard of care

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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)

Special population of interest

Immunocompromised

Hepatic impaired

Estimated number of subjects

43

Study design details

Outcomes

The incidence of "clinically relevant hyperfibrinolytic events" in patients receiving octaplas™ will be compared with the incidence rate in patients receiving plasma issued according to institutional standard of care. The incidence of all adverse drug reactions (i.e. transfusion reactions) during the study period among patients receiving octaplas™ in comparison to those receiving plasma issued according to institutional standard of care.

Data analysis plan

This trial was terminated early after FDA released the requirements to conduct the trial. No meaningful results could be obtained based on the limited data obtained.

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)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No