

Prometheus® European liver disease outcome study

Submission date 06/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/06/2012	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
LIV-Prom-01-EU

Study information

Scientific Title

Acronym

HELIOS

Study objectives

To prove the clinical benefit of the treatment with Prometheus® extracorporeal liver support system on the clinical course of patients with severe deterioration of chronic liver disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Severe deterioration of chronic liver disease.

Interventions

Patients will be randomised to either standard medical treatment or to Prometheus® treatment in addition to standard medical treatment.

For more information, please contact Dr Kinan Rifai at Medizinische Hochschule Hannover (tel +49 5115323302) or Dr Andreas Kribben at the address listed below.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Patient survival.

Key secondary outcome(s)

Clinical course of the patient (e.g. length of stay in intensive care/in hospital, number of hospital re-admissions, liver transplantation status, laboratory parameters).

Completion date

31/12/2006

Eligibility

Key inclusion criteria

Patients with severe deterioration of chronic liver disease.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Conditions strongly interfering with the study outcome (e.g. active HCC, extrahepatic malignancy).

Date of first enrolment

01/07/2005

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Germany

Study participating centre

Universitätsklinikum Essen

Essen

Germany

45122 / 30625

Sponsor information

Organisation

Fresenius Medical Care (Germany)

ROR

<https://ror.org/04sk0bj73>

Funder(s)

Funder type

Industry

Funder Name

Fresenius Medical Care (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2012		Yes	No