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Prometheus® European liver disease outcome study

Submission date	Recruitment status	[_] Prospectively registered
06/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/06/2012	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Andreas Kribben

Contact details
Universitätsklinikum Essen
Hufelandstr. 56
Essen
Germany
45122 / 30625
+49 2017232552
andreas.kribben@uni-essen.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Patient survival.

Secondary outcome measures
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).

Overall study start date
01/07/2005

Completion date
31/12/2006

Eligibility

Key inclusion criteria
Patients with severe deterioration of chronic liver disease.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

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)

Sponsor details
Else-Kröner-Str. 1
Bad Homburg
Germany
61352
justyna.kozik-jaromin@fmc-ag.com

Sponsor type
Industry

ROR
https://ror.org/04sk0bj73

Funder(s)

Funder type
Industry

Funder Name
Fresenius Medical Care (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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