

Recompensation of exacerbated liver insufficiency with hyperbilirubinaemia and/or encephalopathy and/or renal failure

Submission date 17/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/02/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/02/2019	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00614146

Protocol serial number

1438

Study information

Scientific Title

Recompensation of Exacerbated Liver Insufficiency with hyperbilirubinaemia and/or Encephalopathy and/or renal Failure

Acronym

RELIEF

Study objectives

Patients with Molecular Adsorbents Recirculation System (MARS®) treatments in addition to standard medical treatment show a significant improvement in 28-day transplant-free survival.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Freiburg Ethics Commission International (first review) on the 02/04/2003. Local Ethics Committee approval sought for every study site.

Study design

Randomised prospective open controlled non-blinded two-armed study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Recent clinical severe decompensation of a presumed cirrhosis related to a precipitating event

Interventions

Comparison of standard medical treatment (SMT) for acute-on-chronic liver failure versus MARS® liver support therapy in addition to SMT.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

28-day transplant-free survival

Key secondary outcome(s)

1. 28-day survival regardless of transplantation
2. 84-day survival
3. In-hospital mortality
4. Time course of clinical state (number and severity of complications, vital signs, scoring systems, laboratory tests)
5. Economic analysis

Completion date

01/09/2008

Eligibility

Key inclusion criteria

1. Signed written informed consent by patient or next of kin
2. Age greater than 18 years
3. Patients with a recent clinical severe decompensation of a presumed cirrhosis (based on clinical evaluation or radiological imaging) related to a precipitating (trigger) event (e.g. infection, bleeding, alcohol abuse)
4. Intrahepatic cholestasis (bilirubin greater than 5 mg/dl or greater than 85 µmol/l, respectively) without evidence of extrahepatic origin and at least one of the following three:
 - 4.1. Hepatorenal syndrome (impaired renal function with creatinine greater than 1.5 mg/dl or greater than 133 µmol/l without evidence of reduced vascular volume [e.g. central venous pressure {CVP} greater than 8 cm H₂O] and no evidence of pre-existing renal failure)
 - 4.2. Hepatic Encephalopathy greater than or equal to II°
 - 4.3. Progressive Hyperbilirubinaemia: defined as a more than 50% increase of bilirubin before enrolment, whether in referral or currently in hospital up to a level of greater than 20 mg/dl (or greater than 340 µmol/l)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Progressive jaundice and deterioration as a natural course of a chronic liver disease without precipitating (trigger) event
2. Severe thrombocytopenia (platelet count less than or equal to 50 glutamic pyruvic transaminase [GPT]/l)
3. Severe coagulopathy (international normalised ratio [INR] greater than 2.3)
4. Need for renal replacement therapy within three days prior to enrolment
5. Severe infection without antibiotic treatment for at least 24 hours. Uncontrolled bacterial infection.
6. Active bleeding within 48 hours prior to enrolment
7. Proven hepatocellular carcinoma (HCC) greater than 4 cm or infiltration of portal vein or acute portal vein thrombosis
8. Severe cardiopulmonary disease (New York Heart Association [NYHA] greater than or equal to 2)

9. Pregnancy/lactation
10. Mean arterial pressure (MAP) less than 60 mmHg despite vasopressor agents (norepinephrine greater than 1 µg/kg/min) for blood pressure support
11. Overt clinical evidence for disseminated intravascular coagulation (DIC)
12. Clinical evidence for coma of non-hepatic origin
13. Extra-hepatic cholestasis
14. Severe intrinsic renal disease
15. Extended surgical procedure within the last four weeks or unsolved surgical problems
16. Known human immunodeficiency virus (HIV) infection

Date of first enrolment

16/04/2003

Date of final enrolment

01/09/2008

Locations

Countries of recruitment

United Kingdom

Austria

Belgium

Denmark

France

Germany

Italy

Spain

Switzerland

Study participating centre

Hospital General Universitario

Madrid

Spain

28007

Sponsor information

Organisation

Gambro Lundia AB (Sweden)

ROR

<https://ror.org/05mw5ed57>

Funder(s)

Funder type

Industry

Funder Name

Gambro Lundia AB (Sweden)

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	01/03/2013	07/02/2019	Yes	No