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

Submission date 17/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/02/2006	**Overall study status** Completed	
Last Edited 07/02/2019	**Condition category** Digestive System	

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00614146

Secondary identifying numbers
1438

Study information

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

Acronym
RELIEF

Study hypothesis
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Condition
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 measure
28-day transplant-free survival

Secondary outcome measures
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

Overall study start date
16/04/2003

Overall study end date
01/09/2008

Eligibility

Participant 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
172

Participant 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

Recruitment start date
16/04/2003

Recruitment end date
01/09/2008

Locations

Countries of recruitment
Austria

Belgium

Denmark

France

Germany

Italy

Spain

Switzerland

United Kingdom

Study participating centre
Hospital General Universitario
Madrid
Spain
28007

Sponsor information

Organisation
Gambro Lundia AB (Sweden)

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Sponsor type
Industry

Website
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ROR
https://ror.org/05mw5ed57

Funder(s)

Funder type
Industry

Funder Name
Gambro Lundia AB (Sweden)

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