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Prospective study of Molecular Adsorbents Recirculating System (MARS) therapy in chronic stable hepatic dysfunction

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/04/2015	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
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

Secondary identifying numbers
N0077132415

Study information

Scientific Title
Prospective study of Molecular Adsorbents Recirculating System (MARS) therapy in chronic stable hepatic dysfunction

Study objectives
To test the hypothesis that Molecular Adsorbents Recirculating System (MARS) therapy could be used as a treatment for stable chronic alcoholic 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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic alcoholic liver disease

Interventions
Patients with stable chronic alcoholic liver disease currently abstinent will be recruited from hepatology out-patient clinics. They will be randomised to a control non-treatment group or to MARS therapy. Those in the MARS group will be further randomised to group A or B. Those in group B will receive MARS every two weeks. The patients will be studied for 8 weeks. Vascular access would be by tunnelled cuffed right internal jugular dual lumen catheter inserted by a nephrologist under radiological screening. Hepatic encephalopathy, quality of life and symptom assessment will be sampled pre and post MARS treatments and in the non-MARS group at inclusion, 4 and 8 weeks. Portal pressure studies will be measured at the inclusion and the end of the study period. Systemic haemodynamics will be measured using a finometer.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Quality of life and symptom load
2. Level of hepatic encephalopathy and biochemical parameters
3. Level of portal hypertension and systemic haemodynamics

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2004

Completion date
01/10/2007

Eligibility

Key inclusion criteria
Patients with stable alcoholic liver disease who are currently abstinent from alcohol.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2004

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Southern Derbyshire Acute Hospitals NHS Trust
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Southern Derbyshire Acute Hospitals NHS Trust (UK)

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