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European trial of free light chain removal by extended haemodialysis in cast nephropathy

Submission date 10/07/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/03/2008	**Overall study status** Completed	
Last Edited 19/03/2020	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00700531

Clinical Trials Information System (CTIS)
2007-003968-22

Protocol serial number
1.0

Study information

Scientific Title
European trial of free light chain removal by extended haemodialysis in cast nephropathy

Acronym
EuLITE

Study objectives
Free light removal by extended haemodialysis aids recovery of renal function in patients with cast nephropathy.

On 29/01/10 Denmark was added and Italy and Poland removed from the countries of recruitment. The overall trial end date was extended from 01/09/09 to 01/01/2012.

On 12/04/2011 the overall trial end date for this trial was extended from 01/01/2012 to 31/12/2014. Denmark was removed from the countries of recruitment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Office for Research Ethics Committees (COREC), 04/02/2008, ref: 07/H1307/133

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple myeloma, acute renal failure and cast nephropathy

Interventions
All patients will receive standardised chemotherapy (velcade based regime). At enrolment the patients are randomised to receive either standard dialysis or free light chain (FLC) removal haemodialysis. FLC removal HD is undertaken using the Gambro HCO 1100 dialyser. Dialysis sessions are longer (8 hours versus 4 hours) and more frequent than the conventional dialysis received by the control arm. Standard dialysis (control arm) is that used for the management of patients with acute renal failure 4 hours, three times per week.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Velcade-based chemotherapy

Primary outcome(s)
Independence of haemodialysis, at three months from enrolment.

Key secondary outcome(s)
1. Investigation of the efficiency of extended haemodialysis (HD) using the Gambro HCO 1100 to result in sustained reductions in sFLC concentrations versus a standard dialysis at days 5, 12 and 21
2. Comparison of the duration of HD before renal recovery
3. Investigation of multiple myeloma response to chemotherapy and suitability for stem cell transplantation at monthly intervals
4. Mortality, using Kaplan-Meier analysis

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Dialysis dependent acute renal failure (estimated glomerular filtration rate [eGFR] less than 15 ml/min/1.73 m^2)
2. Fulfils diagnostic criteria for the diagnosis of symptomatic de novo multiple myeloma
3. Abnormal serum free light chain (FLC) ratio
4. Myeloma kidney demonstrated on a renal biopsy (cast nephropathy)
5. Ability to give informed consent to partake in study
6. Aged 18 years or older, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Known advanced chronic renal failure (chronic kidney disease [CKD] stage IV; eGFR less than 30 ml/min/1.73 m^2) or evidence of significant chronic damage on renal biopsy
2. Amyloidosis or light chain deposition disease on renal biopsy
3. Previous treatment of multiple myeloma with chemotherapy
4. Haemodynamic instability that precludes unsupported dialysis
5. Significant cardiac disease:
5.1. Myocardial infarction within six months
5.2. Unstable angina

5.3. New York Heart Association (NYHA) class III or IV heart failure
5.4. Clinically significant pericardial disease
5.5. Cardiac amyloidosis
6. Advanced disease or significant co-morbidity with poor short term prognosis, necessitating palliation and no active or disease specific treatment
7. Inability to give informed consent
8. History of allergic reaction to compounds containing boron or mannitol
9. History of peripheral neuropathy or neuropathic pain (grade two or higher)
10. Clinically significant liver dysfunction (bilirubin greater than 1.8 mg/dl [30 umol/L])
11. Known human immunodeficiency virus (HIV) infection
12. Active uncontrolled infection
13. Pregnant/lactating women

Date of first enrolment
01/09/2007

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
United Kingdom

England

Germany

Study participating centre
Queen Elizabeth Medical Centre
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
University Hospital Birmingham NHS Foundation Trust (UK)

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Industry

Funder Name
Gambro Dialysatoren GmbH (Germany) (ref: study number 1454)

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	01/04/2019		Yes	No
Protocol article	protocol	28/09/2008		Yes	No