

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

Submission date 10/07/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 26/03/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/03/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

ClinicalTrials.gov (NCT)
NCT00700531

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

Study design

Randomised controlled trial

Primary study design

Interventional

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 m²)
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 m²) 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