# MyEloma Renal Impairment Trial: adjunctive plasma exchange in patients with newly diagnosed multiple myeloma and acute renal failure

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
21/09/2000		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
21/09/2000	Completed  Condition category	Results		
Last Edited		<ul><li>Individual participant data</li></ul>		
25/10/2022	Cancer	Record updated in last year		

### Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-plasma-exchange-in-patients-with-newly-diagnosed-multiple-myeloma-and-kidney-failure

# Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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# Additional identifiers

EudraCT/CTIS number

IRAS number

### ClinicalTrials.gov number

NCT00416897

### Secondary identifying numbers

C7625/A2879

# Study information

### Scientific Title

A randomised controlled trial of adjunctive plasma exchange in patients with newly diagnosed multiple myeloma and acute renal failure

### Acronym

**MERIT** 

### Study objectives

As of 10/12/2009 this record was updated; all details can be found in the relevant fields under the above update date.

### Added as of 10/12/2009:

Does the addition of plasma exchange (PE) to chemotherapy increase the likelihood of renal recovery in patients with acute renal failure associated with newly diagnosed myeloma?

### 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

Myeloma

### **Interventions**

Plasma exchange in addition to standard chemotherapy versus standard chemotherapy alone.

### Added as of 10/12/2009:

Chemotherapy (ALL patients): two 4-day courses of dexamethasone (d1-12), followed by four cycles of vincristine, Adriamycin and dexamethasone (VAD) (d17-83), with appropriate supportive therapy. Treatment after 100 days will be according to local preference.

Plasma exchange (patients randomised to PE): 7 plasma exchanges within the first two weeks of entry (at least 4 within the first week). Method of plasma exchange will be by either cytocentrifugation or plasma filtration, according to local practice.

### Intervention Type

Other

### **Phase**

Not Applicable

### Primary outcome measure

Added as of 10/12/2009:

Proportion of patients alive and dialysis-independent at 100 days.

### Secondary outcome measures

Added as of 10/12/2009:

- 1. To determine whether addition of plasma exchange to chemotherapy affects overall survival
- 2. To assess the impact of the addition of plasma exchange to chemotherapy on patients' quality of life
- 3. To assess the value of renal histology in predicting recovery of renal function
- 4. To assess the value of serum free light chain assay in determining response of the myeloma to chemotherapy and recovery of renal function in patients with renal failure

### Overall study start date

01/01/2004

### Completion date

31/12/2008

# **Eligibility**

### Key inclusion criteria

Patients with newly diagnosed myeloma and acute renal failure, aged 18 years or over

### Added as of 10/12/2009:

- 1. Newly diagnosed myeloma
- 2. Acute renal failure (creatinine greater than 500 mmol/l, urine output less than 400 ml/d or requiring dialysis)
- 3. Aged 18 years or over, either sex
- 4. Written informed consent
- 5. No previous chemotherapy for myeloma
- 6. No significant intrinsic renal disease unrelated to myeloma

### Participant type(s)

### **Patient**

### Age group

Adult

### Lower age limit

18 Years

### Sex

Both

### Target number of participants

280 (added 10/09/2007)

### Key exclusion criteria

Does not comply with above inclusion criteria

### Date of first enrolment

01/01/2004

### Date of final enrolment

31/12/2008

# **Locations**

### Countries of recruitment

England

**United Kingdom** 

# Study participating centre

**Renal Unit** 

London United Kingdom W12 0HS

# **Sponsor information**

### Organisation

Imperial College London (UK)

### Sponsor details

c/o Clinical Trials Research Unit University of Leeds 17 Springfield Mount Leeds England United Kingdom LS2 9NG

### Sponsor type

University/education

### Website

http://www3.imperial.ac.uk/

### **ROR**

https://ror.org/041kmwe10

# Funder(s)

### Funder type

Charity

### **Funder Name**

Leukaemia Research Fund (UK)

### **Funder Name**

Cancer Research UK (CRUK) (UK)

### Alternative Name(s)

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

Other non-profit organizations

### Location

**United Kingdom** 

# **Results and Publications**

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

# **Individual participant data (IPD) sharing plan**Not provided at time of registration

# IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes