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

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|---|---|---|
| **Submission date**<br>21/09/2000 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>21/09/2000 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>25/10/2022 | **Condition category**<br>Cancer | [_] Individual participant data<br>[_] 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

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## Additional identifiers

**ClinicalTrials.gov (NCT)**
NCT00416897

**Protocol serial number**

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

### Study type(s)
Treatment

### 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(s)
Added as of 10/12/2009:
Proportion of patients alive and dialysis-independent at 100 days.

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

**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**
United Kingdom

England

**Study participating centre**
**Renal Unit**
London
United Kingdom
W12 0HS

# Sponsor information

**Organisation**
Imperial College London (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

### 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 |