

## (MyEloma Renal Impairment Trial)

### **A randomised controlled trial of adjunctive plasma exchange in patients with newly diagnosed multiple myeloma and acute renal failure (ISRCTN37161699) from the Renal Association and UK Myeloma Forum.**

#### **Introduction**

MERIT is a new, multicentre, randomised controlled phase III trial, funded by the Leukaemia Research Fund and Cancer Research UK, and is included in the National Cancer Research Network Trials Portfolio.

#### **Primary question**

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?

#### **Primary endpoint**

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

#### **Secondary aims**

- To determine whether addition of plasma exchange to chemotherapy affects overall survival
- To assess the impact of the addition of plasma exchange to chemotherapy on patients' quality of life
- To assess the value of renal histology in predicting recovery of renal function
- 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.

#### **Main eligibility criteria**

- Newly diagnosed myeloma
- Acute renal failure (creatinine  $>500\mu\text{mol/l}$ , urine output  $<400\text{ ml/d}$  or requiring dialysis)
- Aged 18 years or over
- Written informed consent
- No previous chemotherapy for myeloma
- No significant intrinsic renal disease unrelated to myeloma.

#### **Intervention**

Chemotherapy +/- plasma exchange.

*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 cyto centrifugation or plasma filtration, according to local practice.

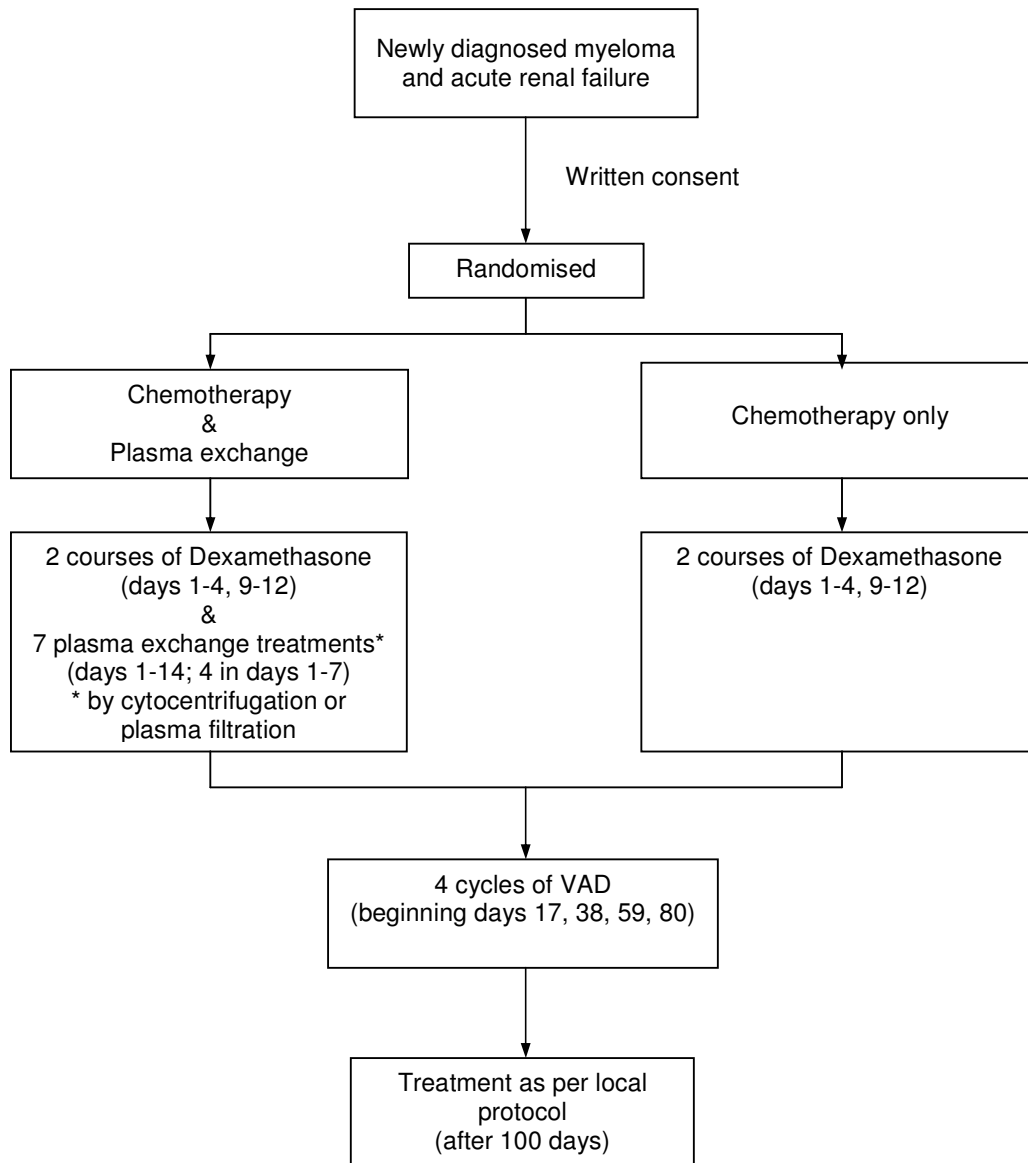
#### **Sample size**

- 286 patients over a five year recruitment period
- designed to detect an absolute improvement in recovery of renal function of 20% (from 20% in the no plasma exchange group to 40% with plasma exchange).

#### **Current status**

Open to recruitment. All nephrologists and haematologists treating myeloma patients with acute renal failure are welcome to participate in the trial. LREC packs are available from the Clinical Trials and Research Unit at the University of Leeds.

# Trial Design



**Clinical co-ordinators:** Dr Gill Gaskin ([g.gaskin@ic.ac.uk](mailto:g.gaskin@ic.ac.uk)), Dr Judith Behrens ([judith.behrens@epsom-sthelier.nhs.uk](mailto:judith.behrens@epsom-sthelier.nhs.uk)), Dr Graham Jackson ([graham.jackson@ncl.ac.uk](mailto:graham.jackson@ncl.ac.uk)), Dr Neil Iggo ([neil.iggo@bsuh.nhs.uk](mailto:neil.iggo@bsuh.nhs.uk)) and Dr Mark Drayson ([m.t.drayson@birmingham.ac.uk](mailto:m.t.drayson@birmingham.ac.uk)).

**We welcome participation from all interested centres.**

**To register interest in the trial and to receive a protocol and LREC pack, complete and return the attached reply slip. For further information contact:**

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**MERIT - MyEloma Renal Impairment Trial**

**To register interest in the trial and to receive a protocol and LREC pack, please complete this form and fax back to CTRU.**

**Centre:** .....

I am interested in participating in this trial and would like to apply for LREC approval in my centre.

**Names of consultants at my centre who will be involved with the trial**

**\*Please indicate lead clinician with an asterisk.**

Title	Initials/First name	Surname	Specialty (Nephrology/ Haematology)	Email address

**Name and contact details of person for CTRU to liaise with about LREC application:**

Name	
Position	
Address	
Telephone number	
Email address	

Approximately how many myeloma patients with acute renal failure would you be able to randomise per year **from your centre?**

Please fax back to Jen Lewis at the Clinical Trials and Research Unit, University of Leeds.  
**Fax number: 0113 343 1471**

**Many thanks for your co-operation**