ISRCTN37161699 https://doi.org/10.1186/ISRCTN37161699

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

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

Contact details
Renal Unit
Imperial College School of Medicine
Department of Medicine
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0HS

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, 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

Not provided at time of registration

Study outputs

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