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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
21/09/2000		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
21/09/2000 Last Edited	Completed Condition category	Results		
		Individual participant data		
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, 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

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