ISRCTN03001669 https://doi.org/10.1186/ISRCTN03001669

European Community SYStemic VASculitis TRIALs group

Submission date	Recruitment status	[_] Prospectively registered
31/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/02/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/08/2008	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.vasculitis.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
ECSYSVASTRIAL

Study objectives
Plasma exchange is superior to high dose intravenous methylprednisolone in the treatment of severe renal vasculitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the Cambridge Local Research Ethics Committee in March 1995.

Study design
Interventional, randomised, controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
ANCA associated vasculitis

Interventions
Plasma exchange versus high dose intravenous methyl prednisolone

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Methyl prednisolone

Primary outcome measure
Renal recovery at three months

Secondary outcome measures
End stage renal disease at one year, severe adverse events

Overall study start date
01/03/1995

Completion date
31/01/2001

Eligibility

Key inclusion criteria
1. New diagnosis of Wegener granulomatosis (WG), micropolyarteritis (MP) or its renal-limited variant, in accordance with the Chapel Hill Consensus criteria, with active vasculitis, as indicated by the presence of active necrotising glomerulonephritis on renal biopsy
2. Anti-neutrophilic cytoplasmic antibodies (ANCA) positivity: either a typical cytoplasmic-ANCA pattern by immunofluorescence test (IIF), and/or positivity in the proteinase-3 enzyme-linked immunosorbent assay (Pr3 ELISA), or positivity in the myeloperoxidase (MPO) ELISA, with or without perinuclear-ANCA (ANCA result will be confirmed by a nominated reference laboratory)
3. Biopsy-proven necrotising and/or crescentic glomerulonephritis, in the absence of another defined glomerulopathy, with severe renal impairment as defined by either:
3.1. Oliguria (less than 400 ml/24 hr) or
3.2. Intention to commence dialysis within 48 hours of admission

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Aged less than 18 or over 80
2. Inadequate contraception in women of child-bearing age
3. Pregnancy
4. Usually exclude patients with previous malignancy (unless agreed with trial coordinators)
5. Hepatitis B antigenaemia or detectable anti-hepatitis C virus antibody
6. Known anti-human immunodeficiency virus (anti-HIV) (HIV testing is not a requirement for this trial)

7. Diagnosis of Churg-Strauss syndrome, Henoch-Schonlein purpura, rheumatoid vasculitis, mixed essential cryoglobulinaemia, systemic lupus erythematosus, or the presence of circulating anti-glomerular basement membrane (anti-GBM) antibodies and linear gamma G immunoglobulin (IgG) staining of the GBM on renal biopsy, with intent to treat as anti-GBM mediated nephritis
8. Life-threatening non-renal manifestations of vasculitis, including alveolar haemorrhage requiring mechanical ventilation within 24 hours of admission
9. On dialysis for more than two weeks prior to referral
10. Significant baseline renal impairment: creatinine greater than 200 mmol/l one year or more before presentation
11. A second clearly defined cause of renal failure (e.g. urinary tract obstruction; not acute tubular necrosis [ATN])
12. Previous episode of biopsy-proven necrotising and/or crescentic glomerulonephritis
13. Intravenous methylprednisolone (IVMeP), plasma exchange (PE) or pulsed intravenous cyclophosphamide within the preceding year
14. More than two weeks treatment with oral cyclophosphamide (Cyc) or azathioprine (Aza)
15. More than three months treatment with oral corticosteroids (OCS)
16. Allergy to study medications (excluding prophylactic agents)
17. Previous IVMeP therapy, which exceeds a single dose of 500 mg prior to referral to the participating centre

Date of first enrolment
01/03/1995

Date of final enrolment
31/01/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Box 118
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Addenbrookes Hospital NHS Trust (UK)

Sponsor details

Addenbrookes Hospital
Hills road
Cambridge
England
United Kingdom
CB2 2QQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/055vbxf86

Funder(s)

Funder type
Government

Funder Name
European Union (Belgium) - Biomedical and Health Research Programme (BIOMED) (contract number BMH4-CT97-2328)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/07/2007		Yes	No