

European Community SYStemic VASculitis TRIALs group

Submission date 31/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/02/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/08/2008	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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/055vbx86>

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