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A randomised clinical trial of mycophenolate mofetil versus cyclophosphamide for remission induction in ANCA associated vasculitis

Submission date 28/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/05/2010	**Overall study status** Completed	
Last Edited 09/09/2019	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00414128

Clinical Trials Information System (CTIS)
2006-001663-33

Protocol serial number
4509

Study information

Scientific Title
A randomised clinical trial of mycophenolate mofetil versus cyclophosphamide for remission induction in ANCA associated vasculitis

Acronym
MYCYC

Study objectives
There is a clear need for improved therapy in antineutrophil cytoplasmic antibody (ANCA) associated vasculitis where current treatments are toxic and contribute to poor outcomes. Conventional therapy combines cyclophosphamide with prednisolone but is associated with severe adverse events in 35%, early mortality, malignancy and infertility. Mycophenolate mofetil (MMF) is a newer immunosuppressive drug which has superior efficacy to azathioprine in solid organ transplantation. MMF is an effective alternative to cyclophosphamide in lupus nephritis. Open label studies and retrospective surveys point to the efficacy and low toxicity of MMF in vasculitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
20/05/2008, ref: 07/H0606/136

Study design
Multicentre randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions
140 new patients will be randomised to MMF 2g/day or a European consensus intravenous cyclophosphamide regimen, with the same prednisolone dosing. Following a 6-month induction course all patients will receive consensus remission maintenance treatment with azathioprine and prednisolone.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Mycophenolate mofetil, cyclophosphamide, azathioprine, prednisolone

Primary outcome(s)
Remission rate by 6 months

Key secondary outcome(s))
1. Relapse rate at 18 months
2. Safety

Completion date
01/01/2010

Eligibility

Key inclusion criteria
1. New diagnosis of ANCA-associated systemic vasculitis (AASV) (Wegener's granulomatosis [WG] or microscopic polyangiitis [MPA]) (within the previous six months)
2. Active disease (defined by at least one major or three minor BVAS 2003 items)
3. ANCA positivity (c-ANCA and PR3-ANCA or p-ANCA and MPO-ANCA) or histology confirming active vasculitis from any organ
4. Written informed consent
5. Aged 5 years or older, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Total final enrolment
140

Key exclusion criteria
1. Previous treatment with:
1.1. MMF: more than two weeks ever
1.2. Cyclophosphamide: more than two weeks daily oral or more than 1 pulse of intravenous (IV) CYC (15 mg/kg)
1.3. Rituximab or high dose intravenous immunoglobulin within the last twelve months
2. Active infection (including hepatitis B, C, human immunodeficiency virus [HIV] and tuberculosis)
3. Known hypersensitivity to MMF, azathioprine (AZA) or CYC
4. Cancer or an individual history of cancer (other than resected basal cell skin carcinoma)
5. Females who are pregnant, breast feeding, or at risk of pregnancy and not using a medically

acceptable form of contraception
6. Any condition judged by the investigator that would cause the study to be detrimental to the patient
7. Any other multi-system autoimmune disease including Churg Strauss angiitis, systemic lupus erythematosus (SLE), anti-glomerular basement membrane (anti-GBM) disease and cryoglobulinaemia
8. Active serious digestive system disease (e.g., inflammatory bowel disease)
9. Patients with imminently life threatening vasculitis (diffuse alveolar haemorrhage, intestinal perforation or major haemorrhage, cerebral vasculitis and cardiac vasculitis)
10. Patients with rapidly progressive glomerulonephritis and declining renal function. Defined as estimated glomerular filtration rate (GFR) fall greater than 20% in previous two weeks.
11. GFR less than 15 ml/min at entry or on dialysis

Date of first enrolment
12/03/2007

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Addenbrookes Hospital
Cambridge
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Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Industry

Funder Name
Aspreva (UK)

Results and Publications

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	01/03/2019	09/09/2019	Yes	No
Basic results			16/05/2019	No	No