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Study of alternative regimens of high dose induction therapy for systemic vasculitis

Submission date 05/02/2002	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 05/02/2002	**Overall study status** Stopped	
Last Edited 19/05/2014	**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

Protocol serial number
B0697

Study information

Scientific Title

Acronym
Hi Cy3

Study objectives
Not provided at time of registration

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Systemic vasculitis

Interventions
At entry the patients will be randomised to either:
1. The HiCy3 regime (six tapering pulses of cyclophosphamide over 3.5 months, with the first pulse being 1.6 g/m^2)
2. The spCy regime - standard pulse cyclophosphamide (nine pulses of 15 mg/kg over 6 months)

All patients will receive intravenous methyl prednisolone with each cyclophosphamide pulse plus relatively low dose routine oral steroid. All patients will also receive mesna with each cyclophosphamide pulse, and will progress to a low dose azathioprine consolidation regime, given up to the end of month 18 of total study.

Updated 19/05/2014: this trial was stopped for reasons of poor recruitment in 2009.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Cyclophosphamide, methyl prednisolone, mesna, azathioprine

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date
30/08/2006

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Patients with newly diagnosed systemic vasculitis
2. Patients with a major recent flare and total previous dose of cyclophosphamide less than 70 g

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/02/2001

Date of final enrolment
30/08/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Rheumatology
Birmingham
United Kingdom
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Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration