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

Submission date	Recruitment status	Prospectively registered
05/02/2002	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
05/02/2002	Stopped	☐ Results
Last Edited	Condition category	Individual participant data
19/05/2014	Circulatory System	Record updated in last year

### Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

#### Contact name

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#### Contact details

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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 B15 2TT

# 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