

# Comparison of intermediate and high dose valaciclovir for the prophylaxis of CMV viraemia in allogeneic stem cell transplant recipients

**Submission date**  
12/09/2003

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
12/09/2003

**Overall study status**  
Completed

☐ Statistical analysis plan

☐ Results

**Last Edited**  
30/11/2015

**Condition category**  
Infections and Infestations

☐ Individual participant data

☐ Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Michael Potter

### Contact details

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## Additional identifiers

### Protocol serial number

N0256114044

## Study information

Scientific Title

Comparison of intermediate and high dose valaciclovir for the prophylaxis of CMV viraemia in allogeneic stem cell transplant recipients

### **Study objectives**

Does high does valaciclovir four times daily have greater efficacy in reducing CMV viraemia than valaciclovir in allogeneic stem cell recipients?

### **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**

Infections and Infestations: Cytomegalovirus (CMV) infection

### **Interventions**

Randomised controlled trial.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

1. Rate of CMV viraemia
2. Time to CMV viraemia
3. Incidence of CMV disease
4. Survival

### **Key secondary outcome(s)**

Not provided at time of registration

### **Completion date**

01/07/2004

## **Eligibility**

### **Key inclusion criteria**

110 patients, 55 in each treatment arm.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**Key exclusion criteria**

Does not match inclusion criteria

**Date of first enrolment**

03/07/2002

**Date of final enrolment**

01/07/2004

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

The Royal Free & University Medical School

London

United Kingdom

NW3 2QG

**Sponsor information**

**Organisation**

Department of Health (UK)

**Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

The Royal Free Hampstead NHS Trust (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?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes