

Determining a viral load threshold for pre-emptive therapy for cytomegalovirus infection in transplant patients using real time PCR monitoring

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 14/02/2020	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

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

ClinicalTrials.gov (NCT)

NCT00947141

Protocol serial number

Study information

Scientific Title

Determining a viral load threshold for pre-emptive therapy for cytomegalovirus infection in transplant patients using real time PCR monitoring

Study objectives

The aim of this study is to determine if quantitative measures of CMV viraemia can be applied to improve the treatment of CMV infection, and to evaluate the threshold of CMV viral load for initiation or discontinuation of pre-emptive therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Committee (REC), 20/11/2002, ref: 6077, re-approved on the 16th November following an MHRA audit

Primary study design

Interventional

Study design

Open-label randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cytomegalovirus (CMV) infection

Interventions

Group A: 72 patients with low level CMV reactivation

Group B: 106 patients receiving pre-emptive therapy

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Current information as of 29/07/2009:

1. The number of patients in Group A with a low level of CMV reactivation who subsequently develop a viral load greater than 3000 copies/ml.
- 2, The number of patients in Group B who develop a second episode of a viral load above 3000 copies/ml after therapy has been discontinued at the defined viral load cut-offs.

Initial information at time of registration:

Number of patients receiving another course of therapy because viral load increases above 3000 copies/ml.

Key secondary outcome(s)

Current information as of 29/07/2009:

1. The duration of antiviral therapy needed to treat CMV viraemia
2. The rate of increase in viral load prior to starting pre-emptive therapy
3. Correlation of viral loads with CMV-specific immune function

Completion date

01/04/2011

Eligibility

Key inclusion criteria

178 patients in total: stem cell, renal and liver transplant recipients with CMV reactivation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

05/12/2002

Date of final enrolment

01/04/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

The Royal Free & University Medical School
London
United Kingdom
NW3 2QG

Sponsor information

Organisation

The Royal Free & University College Medical School - Research and Development (UK)

ROR

<https://ror.org/01ge67z96>

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?
Results article	results	29/09/2016		Yes	No