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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

Registration date
12/09/2003

Overall study status
Completed

Last Edited
14/02/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00947141

Secondary identifying numbers
N0256119271

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

Study design
Open-label randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
05/12/2002

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

Age group
Adult

Sex
Both

Target number of participants
178

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
England

United Kingdom

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)

Sponsor details
Medical School Admin Offices
Room G649
Rowland Hill Street
London
England
United Kingdom
NW3 2PF

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ge67z96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Royal Free Hampstead NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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