ISRCTN75391842 https://doi.org/10.1186/ISRCTN75391842

CytoMegaloVirus: Alternate donor Study of Pre-Emptive Cellular Therapy

Submission date	Recruitment status	[X] Prospectively registered
02/04/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/04/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
13/03/2019	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-treatment-cytomegalovirus-after-stem-cell-bone-marrow-transplant-cmv-impact

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01220895

Protocol serial number
CM-2009-01

Study information

Scientific Title
A prospective phase I/II study to investigate the efficacy and safety of pre-emptive cytomegalovirus adoptive cellular therapy in patients receiving allogeneic haematopoietic stem cell transplant from an unrelated donor

Acronym
CMV: ASPECT

Study objectives
The study will test the hypothesis that adoptive cellular therapy (ACT) can augment the impaired cytomegalovirus (CMV) immune function post-transplant and reduce the requirement for CMV antiviral drug therapy without causing an increase in graft-versus-host disease (GvHD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submitted to University College London Hospitals Research Ethics Committee (UCLH REC) Alpha for review on 07/05/2009 (ref: 09/H0715/47) – approval pending

Study design
Open-label randomised study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cytomegalovirus

Interventions
Patients will be randomised to receive pre-emptive infusion of gamma-captured CMV-specific T-cells administered upon first CMV PCR+ result, along with standard monitoring and pre-emptive CMV anti-viral drug therapy as required (treatment arm A) or standard CMV anti-viral drug therapy alone (treatment arm B) in the ratio of 2:1.

The patient will be assessed for CMV viraemia on a weekly basis up to 100 days following HSCT. On presentation of CMV viraemia the patient will receive the ACT infusion within 72 hours. They will then be assessed on a weekly basis up to 70 days post-infusion and monthly thereafter up to six months. Patients in the control arm will be followed up on a weekly and monthly basis as before but will not receive the ACT infusion.

Intervention Type
Biological/Vaccine

Phase
Phase I/II

Primary outcome(s)

The percentage of patients with a peak number of circulating CMV-reactive T-cells above 10 x 10^6/l within the first two months post single positive PCR result (or ACT infusion), measured in the first two months following ACT infusion.

Key secondary outcome(s))
1. Incidence and severity of GvHD
2. The earliest detection of CMV-reactive T cells in the peripheral blood
3. Duration of CMV antiviral drug therapy (total days), number of in-patient days and number of reactivation episodes

All measured on a weekly basis for the first 100 days following infusion and then monthly up to 6 months thereafter.

Completion date
01/02/2014

Eligibility

Key inclusion criteria
1. Aged 16 years or older, either sex
2. Allogeneic T-cell depleted (alemtuzumab-containing conditioning regimen) haematopoietic stem cell transplant (HSCT) recipient with CMV seropositive unrelated donor
3. Informed consent:
3.1. Prepared to undergo additional study procedures as per study schedule
3.2. Patient has undergone counselling about risk

To be assessed prior to CMV-specific T cell infusion (for confirmation prior to product release):
4. Donor engraftment (neutrophils greater than 0.5 x 10^9/l)
5. Single positive CMV polymerase chain reaction (PCR) result

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Pregnant or lactating women
2. Co-existing medical problems that would place the patient at significant risk of death due to GvHD or its sequelae
3. Human immunodeficiency virus (HIV) infection

To be assessed prior to CMV-specific T cell infusion (for confirmation prior to product release):
4. Active acute GvHD greater than Grade I
5. Concurrent use of systemic corticosteroids

6. Organ dysfunction as measured by:
6.1. Creatinine greater than 200 uM/l
6.2. Bilirubin greater than 50 uM/l
6.3. Alanine aminotransferase (ALT) greater than 3 x upper limit of normal

Date of first enrolment
01/06/2009

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UCL Cancer Institute
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
Cell Medica Ltd (UK)

ROR
https://ror.org/027q99w81

Funder(s)

Funder type
Industry

Funder Name
Cell Medica Ltd (UK) - provide indemnity, prepare the ACT product and subsidise the performance of immune reconstitution assays

Funder Name
Miltenyi Biotec (Germany) - subsidising some materials and reagents used

Funder Name
Royal Free and University College London (UK) - Haematology Department will pick up additional costs associated with participation

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration