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Cytomegalovirus (CMV) peptide vaccine for patients after stem cell transplantation

Submission date	Recruitment status	[_] Prospectively registered
14/06/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/07/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/09/2019	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Cytomegovirus CMV) is a common virus belonging to the herpes family. It is spread though bodily fluids and can be passed on though close contact. Most cases do not cause symptoms, but it can cause flu-like symptoms and weaken the immune system. Research is currently underway to develop vaccines for CMV. It is possible that these transplants may reactivate an existing CMV infection in the recipient. This carries with it a high risk of disease and death. The aim of this study is to test a novel vaccine for patients that have a stem cell transplantation. To see whether it results in an effective immune response against the infection and therefore preventing it.

Who can participate?
Patients about to undergo a bone marrow transplant and are at high risk of CMV reactivation.

What does the study involve?
Participants are given 4 doses of the new vaccine (CMVpp65 peptide vaccine) every 2 weeks after their transplantation. They are examined for any CMV infection throughout with the final examination nine weeks after the first vaccination.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Ulm, Department of Internal Medicine III (Germany)

When is the study starting and how long is it expected to run for?
June 2011 to April 2015

Who is funding the study?
Federal Ministry of Education and Research, BMBF (Gernany)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2010-018884-40

Protocol serial number
UL-CMV-1

Study information

Scientific Title

Preventive and therapeutic peptide-vaccination against CMV in patients after allogenic bone-marrow or periphere stem cell transplantaion.

Study objectives
Vaccination will result in a better immune response against CMV, thus clearing the viral load.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRB/Local Ethics Committee, Ethikkommission Ulm, 07/02/2006, ref: 15/06

Study design
Non-randomized, single-arm, bi-centric study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Patients received 4 doses of the CMVpp65 peptide vaccine (0.3 miligram each, total 1.2 miligram) subcutaneously at a biweekly intervals. Blood was taken before each vaccination and after the last vaccination.

Intervention Type
Biological/Vaccine

Phase
Phase I

Primary outcome(s)
1. Clearance of the CMV from the peripheral blood
2. Toxicity, measured according to Common Toxicity Criteria (CTC) v4.0, i.e. before each vaccination
3. Physical examination and lab tests for blood count, kidney and liver functions tests - final examination 9 weeks after first vaccination

Key secondary outcome(s))
Evaluation of the frequency of CMV specific T cells and titers of CMV specific antibodies, via ELISPOT and tetramer-based flow cytometry assays

Completion date
01/04/2015

Eligibility

Key inclusion criteria
1. High risk for CMV reactivation: donor CMV negative, recipient CMV positive
or
2. Diagnosis of CMV infection/reactivation after allogeneic bone marrow transplantation
and
3. HLA-A2 expression
4. CD4 cell count > 50/mcl
5. Karnofsky index > 70 or ECOG-Status 0-II
6. Age > 18 years
7. Survival time at least 6 months
8. Sufficient renal function (creatinine and BUN < 3fold of the upper limit)
9. Sufficient liver function tests (SGOT/ SGPT/ < 3fold of the upper limit)
10. Compliance of the patient
11. Informed consent must be obtained in written form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
10

Key exclusion criteria
1. Severe, overt Graft versus Host Disease (GvHD)• > 30 mg/day Prednisolon p.o. or i.v.
2. CNS involvement, severe psychiatric disease
3. Severe partial or global respiratory failure
4. Clinically overt cardiac failure (NYHA stage >=III)
5. Pregnancy or breast feeding
6. Females with no sufficient contraception
7. Contraindications against study therapeuticals (including galenic substances)

Date of first enrolment
01/07/2011

Date of final enrolment

31/01/2012

Locations

Countries of recruitment
Germany

Study participating centre
University of Ulm, Department of Internal Medicine III
Albert-Einstein-Allee 23
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Germany
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Study participating centre
University of Heidelberg, Department of Internal Medicine V
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Sponsor information

Organisation
University Hospital Ulm

ROR
https://ror.org/05emabm63

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2017	11/09/2019	Yes	No