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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?
1. Professor Michael Schmitt (scientific)
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2. Professor Jochan Greiner (scientific)
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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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**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 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 |