

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

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

Plain English summary of protocol

Background and study aims

Cytomegalovirus (CMV) is a common virus belonging to the herpes family. It is spread through bodily fluids and can be passed on through 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 (Germany)

Who is the main contact?

1. Professor Michael Schmitt (scientific)
michael.schmitt@med.uni-heidelberg.de

2. Professor Jochan Greiner (scientific)
jochen.greiner@uniklinik-ulm.de

Contact information

Type(s)

Scientific

Contact name

Prof Michael Schmitt

Contact details

Cellular Immunotherapy, GMP Core Facility
Department of Internal Medicine V
University Hospital of Heidelberg
Im Neuenheimer Feld 410
Heidelberg
Germany
69120
+49-(0)6221-56-6614
michael.schmitt@med.uni-heidelberg.de

Type(s)

Scientific

Contact name

Prof Jochen Greiner

Contact details

University Hospital Ulm
Department of Internal Medicine III
Albert-Einstein-Allee 23
Ulm
Germany
89081
0049 731 5004 5709
jochen.greiner@uniklinik-ulm.de

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 periphery stem cell transplantation.

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

Primary study design

Interventional

Study design

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

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 milligram each, total 1.2 milligram) subcutaneously at 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 therapeutics (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

Ulm

Germany

89081

Study participating centre

University of Heidelberg, Department of Internal Medicine V

Im Neuenheimer Feld 410

Heidelberg

Germany

69120

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