

# Cytomegalovirus peptide vaccination in end-stage renal disease

|                                        |                                                              |                                                      |
|----------------------------------------|--------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>23/01/2017   | <b>Recruitment status</b><br>No longer recruiting            | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                              | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>28/04/2017 | <b>Overall study status</b><br>Completed                     | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                              | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>06/06/2023       | <b>Condition category</b><br>Urological and Genital Diseases | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

### Background and study aims

Loss of kidney function, known as end-stage chronic kidney disease, is the most common reason for needing a kidney transplant. Patients receiving kidney transplants are at high risk of cytomegalovirus (CMV) infection, particularly during the first 3 months after transplantation due to the use of immunosuppressant medications, which prevent the body's immune system from attacking the new kidney. Today, antiviral prophylaxis (treatment to prevent viral infection) is standard of care at least in high-risk cases where the kidney donor is CMV-positive and the recipient is CMV-negative. However, preventative treatment of CMV is often linked to side effects as hematological toxicity (a decrease in bone marrow and blood cells), requiring reduction of immunosuppression. The aim of this study is to prove the safety and feasibility of a CMV vaccine in CMV-negative end-stage kidney disease patients on the kidney transplant waiting list.

### Who can participate?

CMV-negative end-stage kidney disease patients on the kidney transplant waiting list, aged 18 and over

### What does the study involve?

All participants receive an injection with a CMV vaccine four times every two weeks. A follow-up visit takes place 14 days after the last vaccination. At each study visit blood samples are taken for laboratory analysis and participants receive a clinical check-up.

### What are the possible benefits and risks of participating?

There are no direct benefits. The risks include side effects of vaccination such as local inflammation and side effects of blood taking such as hematoma (bruising).

### Where is the study run from?

University Hospital Heidelberg (Germany)

### When is the study starting and how long is it expected to run for?

May 2012 to August 2016

Who is funding the study?

1. Renal Center Heidelberg (Germany)
2. Else Kröner-Fresenius-Stiftung (Germany)
3. University Hospital Heidelberg (Germany)

Who is the main contact?

Mrs Claudia Sommerer

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Claudia Sommerer

### Contact details

Renal Center Heidelberg  
Im Neuenheimer Feld 162  
Heidelberg  
Germany  
69120

## Additional identifiers

### Clinical Trials Information System (CTIS)

2012-002486-35

### Protocol serial number

RCHD-CMV-1001

## Study information

### Scientific Title

Peptide vaccination against cytomegalovirus (CMV) in CMV seronegative end-stage renal disease patients

### Acronym

CMV PepVac

### Study objectives

The aim of this study is to test the safety and feasibility of cytomegalovirus (CMV) peptide vaccination.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethikkommission des Universitätsklinikums Heidelberg, 10/10/2013, ref: AFmo-256/2013

## Primary study design

Interventional

## Study design

Prospective non-randomized single-arm single-center interventional investigator-initiated phase I study

## Study type(s)

Prevention

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

Renal failure

## Interventions

Patients are stepwise enrolled in a 5+5 phase I study design. All patients will have 300 µg of CMVpp65-derived peptide vaccination subcutaneously four times every two weeks in the proximal upper leg. The first five patients have to pass all four vaccinations and safety assessments prior to enrolment of the last five patients. End of study is 14 days after the last vaccination.

## Intervention Type

Biological/Vaccine

## Phase

Phase I

## Drug/device/biological/vaccine name(s)

Not provided at time of registration

## Primary outcome(s)

Frequency of adverse events due to CMV peptide vaccination within the study time of 56 days

## Key secondary outcome(s)

1. Serious adverse events classified as CTC (common toxicity criteria) within the study period of 56 days
2. Adverse events classified as CTC (common toxicity criteria) within the study period of 56 days
3. Immunological response, assessed by seroconversion of CMV IgG
4. Induction of a CMV specific immune response, assessed by:
  - 4.1. CMV specific T cells (tetramer staining)
  - 4.2. IFN $\gamma$  release (ELISPOT)

## Completion date

31/08/2016

## Eligibility

### Key inclusion criteria

1. Aged 18 years and over
2. End-stage renal disease
3. CMV IgG seronegative

4. HLA-A2 expression positivity
5. Liver function tests below the threefold of the normal upper values
6. No active infection
7. Expected compliance
8. Provision of written informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**Key exclusion criteria**

1. Prednisolone therapy >25 mg/d
2. Planned vaccination of other indication within the study period

**Date of first enrolment**

17/02/2015

**Date of final enrolment**

31/05/2016

**Locations****Countries of recruitment**

Germany

**Study participating centre**

**University Hospital Heidelberg**

Department of Nephrology

Renal Center Heidelberg

Im Neuenheimer Feld 162

Heidelberg

Germany

69120

**Sponsor information**

**Organisation**

Renal Center Heidelberg

**ROR**

<https://ror.org/013czdx64>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Renal Center Heidelberg

**Funder Name**

Else Kröner-Fresenius-Stiftung

**Alternative Name(s)**

Else Kroner-Fresenius Foundation, Else Kroener-Fresenius-Stiftung, Else Kröner Fresenius-Stiftung, EKFSStiftung, StiftungEKFS, EKFS

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Germany

**Funder Name**

University Hospital Heidelberg

**Results and Publications****Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available due to data protection law in Germany.

**IPD sharing plan summary**

Not expected to be made available

Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 04/02/2021   | 06/06/2023 | Yes            | No              |