

Cytomegalovirus peptide vaccination in end-stage renal disease

Submission date 23/01/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/04/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 06/06/2023	Condition category 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

EudraCT/CTIS number

2012-002486-35

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

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

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet (German version only)

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 measure

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

Secondary outcome measures

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 γ release (ELISPOT)

Overall study start date

01/05/2012

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

10

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

Sponsor details

Im Neuenheimer Feld 162

Heidelberg

Germany

69120

Sponsor type

Hospital/treatment centre

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 Kroener-Fresenius-Stiftung, Else Kröner Fresenius-Stiftung, Else Kroner-Fresenius Foundation, 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

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

2017 results presented at Kidney Week: <https://www.asn-online.org/education/kidneyweek/2017/program-abstract.aspx?controlId=2768554>

Intention to publish date

31/08/2017

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?
Results article		04/02/2021	06/06/2023	Yes	No