ISRCTN11842403 https://doi.org/10.1186/ISRCTN11842403

Cytomegalovirus peptide vaccination in end-stage renal disease

Submission date	Recruitment status	[_] Prospectively registered
23/01/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/04/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/06/2023	Urological and Genital Diseases	

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

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

Primary study design
Interventional

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. IFNy 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, EKFStiftung, 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?
Results article		04/02/2021	06/06/2023	Yes	No