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Heart failure in patients with advanced chronic kidney disease

Submission date
03/03/2021

Recruitment status
Recruiting

Registration date
16/03/2021

Overall study status
Ongoing

Last Edited
06/01/2026

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The kidneys filter the blood using very specialised blood vessels to remove waste and toxic substances, and returning vitamins, amino acids, glucose, hormones and other vital substances into the bloodstream. The kidneys also help to regulate the fluid volume of the blood. Kidney failure is when kidneys no longer function well enough to meet the needs of daily life. This can worsen to end-stage kidney disease (ESKD) which is when kidney function falls below 10% of normal function. Kidney failure can be treated by haemodialysis. Haemodialysis is a way of replacing some of the functions of your kidney, blood is filtered using an external machine and then returned to the body.

Patients with ESKD who are receiving haemodialysis are at increased risk for development of heart failure (HF). Heart failure (HF) is a frequent cause of death and disability in patients.

It is not easy to distinguish HF from water overload in patients with ESKD, and many patients on haemodialysis have exercise limitations unrelated to HF. Therefore the traditional definition of HF, which is based on exercise ability, is less useful in this population.

The study team have suggested two new definitions of heart failure. This study will test whether these newer definitions are able to better identify patients with a higher risk of heart failure.

Who can participate?
Clinically stable adult patients being treated by chronic hemodialysis in the collaborating haemodialysis units

What does the study involve?
Patients treated by haemodialysis in 6 collaborating haemodialysis units will be examined at the General University Hospital in Prague every 6-12 months until kidney transplantation. The examination at each session will involve basic history, clinical assessment of heart failure (HF) symptoms (through scans of the heart, analysis of the blood vessels, blood samples for markers of heart failure, body composition analysis), and competition of a questionnaire about heart failure.

What are the possible benefits and risks of participating?
A potential benefit is timely diagnosis of heart disease that would allow timely treatment. There are no associated risks anticipated.

Where is the study run from?
General University Hospital in Prague (Czech Republic)

When is the study starting and how long is it expected to run for?
From March 2019 to December 2029

Who is funding the study?
Ministry of Health Czech Republic and General University Hospital in Prague (Czech Republic)

Who is the main contact?
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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
CZecking Heart failure in patients with advanced Chronic Kidney Disease (Czech HF-CKD)

Acronym
Czech HF-CKD

Study objectives
1. Newer heart failure (HF) definitions will better identify patients with more advanced structural heart changes, higher morbidity, and mortality. The newer definitions are as follows:
1.1. Modified ADQI XI Workgroup definition (at least 2 criteria of structural heart disease with cut-off values used in the cardiological guidelines)
1.2. Haemodynamic definition, defined as low effective cardiac index (<2.5 l/min/m²) at rest in patients with at least one of the following abnormalities:
1.2.1. Left ventricular hypertrophy
1.2.2. Left ventricular EF <40%
1.2.3. AVF flow volume >1500 ml/min, but in the absence of significant valvular/pericardial disease
1.2.4. Diastolic dysfunction grade 2 or 3
1.2.5. Moderate or severe left atrial dilatation (LAVi >40 ml/m²)
1.2.6. Estimated pulmonary artery systolic pressure >40 mmHg
2. In patients with non-cardiac exercise limitation (orthopedical and neurological problems, myopathy, frailty, etc), the use of a combination of advanced structural heart changes and of elevated NTproBNP level could become an HF surrogate that would lead to a similar risk of endpoints as in the symptomatic HF subjects
3. Careful assessment of dry weight setting will enable us to estimate real-world HF prevalence by excluding simple water overload mimicking HF

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 23/05/2019, protocol amendment approved 23/05/20120, title amendment approved 18/02/2021, Institutional ethics committee of the General University Hospital in Prague (Na Bojišti 1, 128 08 Prague 2, Czech Republic; +420 224 964 131; eticka.komise@vfn.cz), ref: 789/19, protocol amendment ref: 30/20

Study design
Longitudinal prospective single-center observational cohort study with regular assessment of endpoints

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Heart failure in patients with advanced chronic kidney disease

Interventions
This is an observational study of a cohort of patients with advanced chronic kidney disease.

The study will collect basic history, clinical assessment of heart failure (HF) symptoms, and use of the “Prague CKD-HF questionnaire”. The clinical assessment will include the following:
1. Blood samples (full blood count, albumin, total protein, NT-pro brain natriuretic peptide)
2. Expert echocardiography, detailed analysis of the volumes of heart cavities, quantification of valvular disease, diastolic dysfunction according to the recent guidelines, calcification extent, and cardiac output calculation (from the left ventricular outflow tract diameter and velocity-time interval)
3. Hemodialysis arteriovenous fistula flow volume (flow in the feeding brachial artery by duplex ultrasound)
4. Hydration status assessed clinically (effusions, edema) and estimation of central venous pressure by inferior vena cava diameter and collapsibility by bio-impedance
5. Body composition (bio-impedance by Body composition monitor, FMC) including total body water, overhydration, extra- and intracellular water, lean body mass, and fat body mass
6. Arterial stiffness (pulse wave velocity between carotid and femoral arteries using Sphygmocor)
7. Rhythm analysis (sinus rhythm vs. atrial fibrillation) using electrocardiography

In cases of water overload during the examination, dry weight adjustment will be recommended, and the patient invited for another examination within 6 weeks. Only examinations performed at the optimal hydration status will be included.

Participants will be followed up for assessment every 6 to 12 months until kidney transplantation, death, or the end of the study period.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 07/07/2021:

1. Incidence of cardiovascular death measured from patient notes between baseline and the end of the study
2. Worsening of heart failure (defined as worsening by 1 class of New York Heart Association Functional Classification, the incidence of hospitalization for de-compensation, an ejection fraction decrease by ≥10%, or new diagnosis of heart failure) measured using clinical assessment and patient notes every 6-12 months between baseline and the end of the study
3. Incidence of significant cardiovascular morbidity (acute coronary syndrome or stroke) measured from patient notes between baseline and the end of the study

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Previous primary outcome measure:

1. Incidence of death measured from patient notes between baseline and the end of the study
2. Worsening of heart failure (defined as worsening by 1 class of New York Heart Association Functional Classification, the incidence of hospitalization for de-compensation, an ejection fraction decrease by ≥10%, or new diagnosis of heart failure) measured using clinical assessment and patient notes every 6-12 months between baseline and the end of the study
3. Incidence of significant cardiovascular morbidity (acute coronary syndrome or stroke) measured from patient notes between baseline and the end of the study
4. Coronary or valvular intervention (percutaneous or surgical) measured from patient notes between baseline and the end of the study

Key secondary outcome(s))

Current secondary outcome measures as of 07/07/2021:

1. Components of the primary endpoint measured from patient notes between baseline and the end of the study
2. Incidence of other cardiovascular morbidity (stroke, acute leg ischemia, pulmonary embolism, etc.) measured from patient notes between baseline and the end of the study
3. Need for dry weight decrease by >3% of body weight because of overhydration measured by body composition monitor every 6-12 months between baseline and the end of the study
4. Need of coronary or valvular intervention (percutaneous or surgical) measured from electrocardiography and echocardiography every 6-12 months between baseline and the end of the study
5. Incidence of pacemaker/defibrillator implantation measured from patient notes between baseline and the end of the study
6. Coronary or valvular intervention (percutaneous or surgical) measured from patient notes between baseline and the end of the study
7. Incidence of vascular access intervention measured from patient notes between baseline and the end of the study
8. Non-cardiac death measured from patients notes between baseline and the end of the study

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Previous secondary outcome measures:

1. Components of the primary endpoint measured from patient notes between baseline and the end of the study
2. Incidence of other cardiovascular morbidity (stroke, acute leg ischemia, pulmonary embolism, etc.) measured from patient notes between baseline and the end of the study

3. Need for dry weight decrease by >3% of body weight because of overhydration measured by body composition monitor every 6-12 months between baseline and the end of the study
4. Need of coronary or valvular intervention (percutaneous or surgical) measured from electrocardiography and echocardiography every 6-12 months between baseline and the end of the study
5. Incidence of pacemaker/defibrillator implantation measured from patient notes between baseline and the end of the study
6. Incidence of vascular access intervention measured from patient notes between baseline and the end of the study

Completion date
31/12/2029

Eligibility

Key inclusion criteria
1. Treated by chronic hemodialysis in the collaborating haemodialysis units
2. Clinically stable
3. Willing to participate
4. ESKD treated by hemodialysis for at least 3 months
5. Aged >18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
300

Key exclusion criteria
1. Planned kidney transplantation from a living donor within 3 months of the index visit
2. Life expectancy <6 months at the index (first) visit for any reason
3. No dementia

Date of first enrolment
10/06/2019

Date of final enrolment
31/12/2028

Locations

Countries of recruitment
Czech Republic

Study participating centre
General University Hospital
U nemocnice 1
Prague
Czech Republic
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Sponsor information

Organisation
General University Hospital in Prague

ROR
https://ror.org/04yg23125

Funder(s)

Funder type
Government

Funder Name
Ministerstvo Zdravotnictví Ceské Republiky

Alternative Name(s)
Ministry of Health of the Czech Republic, MZCR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Czech Republic

Funder Name
Všeobecná Fakultní Nemocnice v Praze

Alternative Name(s)
General University Hospital in Prague, VFN

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
Czech Republic

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2023	19/02/2025	Yes	No