

eHealth for nephrology in Hannover

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| Submission date 06/07/2019 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 14/07/2019 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 24/02/2020 | Condition category Urological and Genital Diseases | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

The aim of NEPHRO-DIGITAL is to create a regional eHealth platform in the Hannover region that facilitates integrated, cross-sectoral data exchange and includes teleconsultation between outpatient nephrology, primary care, pediatricians and nephrology clinics to reduce communication deficits and prevent data loss, and to enable the creation and implementation of an interoperable clinical decision support system.

Who can participate?

All pediatric and adult nephrologic patients of the region of Hannover can use the eHealth platform.

What does the study involve?

This system is based on input data from multiple sources for early identification of patients with cardiovascular comorbidity and progression of renal insufficiency. Especially patients will be able to enter and access their own data. A decision support system should lead to earlier therapeutic interventions and thereby improve the prognosis of patients as well as their treatment satisfaction and quality of life. The system will be integrated in the two largest German health platforms in university medicine HIGHMed and MIRACUM.

What are the possible benefits and risks of participating?

The possible benefit would be more integration of patient data. There is no risk.

Where is the study run from?

The study is run from Hannover Medical School.

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

The study will take place from January 2020 till December 2022.

Who is funding the study?

The study is funded by the Ministry of Research and Culture of Lower Saxony and the Volkswagen Foundation (Niedersachsen Vorab).

Who is the main contact?

The main contact is Prof. Dr. med. Lars Pape: Pape.Lars@mh.hannover.de

Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

1.0

Study information

Scientific Title

The nephrology eHealth-System of the metropolitan region of Hannover for digitalization of care, establishment of decision support systems and analysis of health care quality

Acronym

NephroDIGITAL

Study objectives

The primary hypothesis underlying the project is that the digitization of nephrology data presented above will result in a significant improvement in patient care and, in addition, will lead to cost savings in the health care system by reducing hospitalization and redundant diagnostics (hospital, nephrologist, general practitioner/pediatrician) and treatment and by improving quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval is not required: The NephroDigital Project has been submitted to the ethics committee of Hannover Medical School. The committee has confirmed that the study can be

carried out without a formal ethics vote as the main aim of the study is to develop new IT interfaces.

Study design

Qualitative interviews

Primary study design

Other

Study type(s)

Other

Health condition(s) or problem(s) studied

Nephrologic diseases

Interventions

Patients and Health care professional will be able to use eHealth system.

The trial has no formal patient inclusion. During the trial, patients will experience an improved IT-environment. Patients will be followed up as long as they use the new IT.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

N/A

Primary outcome(s)

Implementation of a cross-sector electronic case file eFA including teleconsultations and patient access. Indicator: 50% of patients with shared use of eFA after 30 months.

Key secondary outcome(s)

1. Evaluation of care provider needs on data and information sharing, acceptance and feasibility (qualitatively, interviews with GPs / pediatricians) at 30 months.
2. Implementation of a decision support system for GFR deterioration and cardiovascular comorbidities. Indicator: System is implemented at 30 months
3. Comparison of intersectoral treatment quality between Hannover Region and Erlangen. Indicator: Analysis performed at 30 months
4. Reduction of complications of nephrological diseases. Indicator: Reduction of complications requiring inpatient treatment. Indicator: A 10% reduction of hospital expenditure within 30 months compared to a control cohort (historical control patients who did not participate in the program)
5. Reduction in cardiovascular events. Indicator: The number of hospitalizations due to cardiovascular events will be reduced > 10% within 30 months.
6. After the establishment of NEPHRO-DIGITAL, participant quality of life will improve significantly. Indicator: In the mental subscale of the SF-12, 80% of the participating patients will reach values which do not differ from population norm data within 30 months.
7. Is the use of the new digital elements and the quality of life gender-dependent? Does a

migration background play a role in the acceptance of digital medicine? Indicator: Participation rate in subgroups is not significantly different after 30 months.

Completion date

12/12/2022

Eligibility

Key inclusion criteria

All pediatric and adult nephrologic patients in the Region Hannover will be indirectly part of the trial by improving the IT-architecture.

Participant type(s)

All

Healthy volunteers allowed

No

Age group

All

Sex

All

Key exclusion criteria

N/A

Date of first enrolment

01/01/2021

Date of final enrolment

30/09/2022

Locations

Countries of recruitment

Germany

Study participating centre

Hannover Medical School

Carl-Neuberg-Straße 1

Hannover

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D-30625

Sponsor information

Organisation

Hannover Medical School

ROR

<https://ror.org/00f2yqf98>

Funder(s)

Funder type

Government

Funder Name

Volkswagen Stiftung, Ministry of Science and Culture of Lower Saxony

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

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? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 02/09/2019 | | Yes | No |