ISRCTN16755335 https://doi.org/10.1186/ISRCTN16755335

eHealth for nephrology in Hannover

Submission date	Recruitment status	[X] Prospectively registered
06/07/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/07/2019	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/02/2020	Urological and Genital Diseases	[_] 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 Saxoney 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

Contact name
Prof Lars Pape

Contact details
MHH, Carl-Neuberg-Straße 1
Hannover
Denmark
D-30625
+495115323283
Pape.Lars@mh-hannover.de

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Study setting(s)
Internet/virtual

Study type(s)
Other

Participant information sheet
No participant information sheet available.

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2020

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

Age group
All

Sex
Both

Target number of participants
There will by around 300 pediatric and 5000 adult nephrologic patients

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
Germany
D-30625

Sponsor information

Organisation
Hannover Medical School

Sponsor details
Carl-Neuberg-Straße 1
Hannover
Germany
D-30625
+405115320
Pape.Lars@mh-hannover.de

Sponsor type
University/education

Website
http://www.mh-hannover.de

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2019

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