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A programme to spread glomerular filtration rate (eGFR) graph surveillance for the early identification, support and treatment of people with progressive chronic kidney disease

Submission date
10/10/2016

Recruitment status
No longer recruiting

Registration date
11/01/2017

Overall study status
Completed

Last Edited
07/01/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic kidney disease (CKD) is a long-term condition where the kidneys do not work properly. In a healthy person, the kidneys are vital for filtering out the waste products and excess water in the blood, and converting them into urine. In patients suffering from CKD, the kidneys are unable to do this, and so the body is unable to get rid of the waste products building up in the blood. CKD is common, affecting over 10% of the adult population. It is frequently unrecognised since it causes no symptoms in the early stages. CKD often exists together with other conditions, particularly high blood pressure and diabetes. Some people with CKD develop kidney disease that worsens over time (progressive disease). In the most advanced stages, treatment using machines to do the work of the kidneys (dialysis) or transplants are the only way to keep people alive. People with progressive disease who are referred late by their GPs to kidney units treatment have a lower risk of surviving. Late referral is therefore a major, and preventable, cause of harm in these people. Early identification of people with progressive disease would also create opportunities to start treatment to slow disease progression. The aim of this project is to improve the treatment and outcomes of CKD patients at high risk of kidney failure and other complications.

Who can participate?
Patients with chronic kidney disease.

What does the study involve?
Information on each of the participants on pathology computer systems are used to generate a graph of kidney function over time. In cases where the graph shows that kidney function is getting worse, these are highlighted for review by a laboratory scientist. For participants that are identified as being of “high-risk” a paper copy of the graph is sent to the general practitioner with a prompt that further action may be needed. In this way the project takes information already available and highlights trends over time to primary care. The intervention is to be rolled-out sequentially, with renal centres (and their associated pathology laboratories) starting eGFR

graph reporting at staggered time points. Four or five renal centres begin the intervention at each step with a six-month interval between steps.
(Removed 20/05/2019: The start time of the program is chosen randomly.)

What are the possible benefits and risks of participating?
Individual patients do not have any additional testing and there are no significant burdens or risks.

Where is the study run from?
22 NHS sites in the UK

When is the study starting and how long is it expected to run for?
September 2014 to December 2017

Who is funding the study?
Health Foundation (UK)

Who is the main contact?
1. Dr Hugh Gallagher (scientific)
2. Ms Rowena Sampson (public)
Assist@kidneyresearchuk.org

Contact information

Type(s)
Scientific

Contact name
Dr Hugh Gallagher

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St Helier Hospital
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Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
Health Foundation Unique Award Reference Number: 7349

Study information

Scientific Title
A programme to spread eGFR graph surveillance for the early identification, support and treatment of people with progressive chronic kidney disease (ASSIST-CKD): stepped wedge implementation and evaluation of an intervention to reduce late presentation for renal replacement therapy

Acronym
ASSIST-CKD

Study objectives
The aim of this study is to evaluate the implementation of this intervention across a large population served by a number of UK renal centres using a mixed methods approach.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The project was considered by the National Research Ethics Service (South East Coast-Surrey) on 16th January 2015 and determined to be service evaluation, not requiring ethical review by an NHS Research Ethics Committee. The project does not involve allocation to different interventions across patient groups; there are no significant risks or burdens to patients; and outcome data are already routinely collected by the UK Renal Registry.

The intervention was introduced as a local quality improvement project in the Heart of England Foundation Trust in 2012. The subsequent fall in late presentation rate has been documented and published. A number of sites, such as the West Midlands Strategic Clinical Network, are routinely introducing the intervention outside this project on the basis of this evidence.

Primary study design
Interventional

Study design
Current study design as of 20/05/2019:
Quasi-experimental study (changed in Sept 2017)

Previous study design:
Multicentre stepped wedge randomised control study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic kidney disease

Interventions
Reporting of eGFR graphs by pathology laboratories to primary care. The intervention takes the information on pathology computer systems and automatically generates a graph of kidney function over time for individuals. Graphs where the kidney function is deteriorating are flagged for review by a laboratory scientist – for those patients determined to be “high-risk” a paper copy of the graph is sent to the general practitioner with a prompt that further action may be needed. In this way the project takes information already available and highlights trends over time to primary care. Individual patients do not have any additional testing and there are no significant burdens or risks.

The intervention will be rolled-out sequentially, with renal centres (and their associated pathology laboratories) commencing eGFR graph reporting at staggered time points. The plan is for four or five renal centres to begin implementation at each step with a six-month interval between steps. The time of intervention initiation will be randomised.

UPDATE 20/05/2019:
Randomisation proved extremely difficult to follow, with only very few laboratories being able to activate the intervention in the period they were randomised to. Therefore in September 2017 it was decided to proceed with analysis based on a quasi-experimental design, where the study is not considered ‘experimental’ because of lack of randomisation, but there is still account for control periods, a staggered intervention that allows for more robust analysis of possible confounding time effect, and also the inclusion of more controls (non-participants clusters, never randomised, never started on intervention, areas with no similar interventions).

Intervention Type
Other

Primary outcome(s)
Incidence of late presentation for renal replacement therapy, defined as any patient first seen by renal services within 90 days of starting renal replacement therapy. These data will aggregate into six-month time periods, two per calendar year (Jan to June; July to December).

Key secondary outcome(s)
1. The use of temporary vascular access for starting dialysis
2. Estimated Glomerular Filtration Rate (eGFR) measured within two weeks of start of renal replacement therapy (RRT)
3. Mortality at 6 months from start of RRT in new RRT patients
4. The incident rate of end-stage renal disease, measured annually

All outcomes measures are routinely collected by the UK Renal Registry with the exception of vascular access, which is collected annually as part of the Registry’s Multisite Dialysis Access Audit. Routinely collected baseline data will be provided by the UK Renal Registry and baseline referral rates supplied by participating centres. Outcomes will be measured before and during intervention roll-out at each site.

The number of new patient referrals (per quarter) will be recorded as a balancing measure. These data are readily extractable from renal centre appointment systems.

A qualitative evaluation will also be performed with:
1. Semi-structured interviews with laboratory staff, renal centre staff and service commissioners, in order to find out about the drivers and enablers to the intervention being implemented and

also to find out what these groups think the effect of the intervention might be
2. Online survey of GPs receiving the intervention, that is, asking GPs how useful the graph is in identifying people at risk of progressive disease, and how helpful it is in providing education about what to do next
3. Focus groups of primary care staff, where questions will examine in more detail the implementation of the intervention (what happens once the graph arrives in the Practice) and what potential difference the graphs make to patient care

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Patients <65 years with eGFR <50 ml/min/1.73m2
2. Patients >65 years with eGFR <40 ml/min/1.73m2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Participants not fulfilling inclusion criteria.

Date of first enrolment
31/07/2015

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Royal Cornwall Hospital NHS Trust
Royal Cornwall Hospital
2 Penventinnie Lane
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
NHS Lanarkshire Hospitals
Monklands Hospital
Monkscourt Avenue
Airdrie
United Kingdom
ML6 0JS

Study participating centre
Wirral University Teaching Hospitals NHS Trust
Arrowe Park Hospital
Upton
Wirral
United Kingdom
CH49 5PE

Study participating centre
Countess of Chester Hospital NHS Foundation Trust
The Countess Of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre
Doncaster and Bassetlaw Hospitals NHS Foundation Trust
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Liverpool Clinical Laboratories
Aintree University Hospital NHS Trust/Royal Liverpool and Broadgreen University Hospitals NHS Trust
Liverpool
United Kingdom
L69 3GA

Study participating centre
Southport and Ormskirk Hospital NHS Trust
Southport and Formby District General Hospital
Town Lane
Kew
Southport
United Kingdom
PR8 6PN

Study participating centre
Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Road
High Heaton
Newcastle-upon-Tyne
United Kingdom
NE7 7DN

Study participating centre
Southern Health and Social Care Trust
John Mitchel Place
Newry
United Kingdom
BT35 8DR

Study participating centre
Southend University Hospital NHS Foundation Trust
Prittlewell Chase
Westcliff-on-Sea
United Kingdom
SS0 0RY

Study participating centre

South Eastern Health and Social Care Trust
Upper Newtownards Road
Ulster
United Kingdom
BT16 1RH

Study participating centre
Northern Health and Social Care Trust
Services Yard Antrim Area Hospital
45 Bush Road
Antrim
United Kingdom
BT41 2RL

Study participating centre
Betsi Cadwaladr University Health Board
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham
United Kingdom
LL13 7TD

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
Wrythe Lane
Carshalton
London
United Kingdom
SM5 1AA

Study participating centre
Surrey Pathology Services
Royal Surrey County Hospital NHS Foundation Trust/Ashford and St Peter's Foundation Trust /Frimley Health NHS Foundation Trust
Surrey
United Kingdom
GU2 7XX

Study participating centre
Hull and East Yorkshire NHS Foundation Trust
Anlaby Road

Hull
United Kingdom
HU3 2JZ

Study participating centre
Betsi Cadwaladr University Health Board
Ysbyty Gwynedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Western Health and Social Care Trust
106 Irish Street
Derry
United Kingdom
BT47 6SB

Study participating centre
Derby Teaching Hospitals NHS Foundation Trust
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Betsi Cadwaladr University Health Board
Glan Clwyd Hospital
Rhuddlan Road
Bodelwyddan
Rhyl
United Kingdom
LL18 5UJ

Study participating centre
ABM University Health Board
Morriston Hospital
Heol Maes Eglwys
Morriston
Swansea

United Kingdom
SA6 6NL

Study participating centre
City Hospitals Sunderland NHS Foundation Trust
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Sponsor information

Organisation
Kidney Research UK

ROR
https://ror.org/02kx7se86

Funder(s)

Funder type
Charity

Funder Name
Health Foundation

Results and Publications

Individual participant data (IPD) sharing plan
1. Individual patient level data are stored, which can also be analysed at centre level. The repository name is the UK Renal Registry (UKRR): www.renalreg.org
2. Access to the data will not be limited, except patient or centre identifiable information. The process to access data can be found here: https://www.renalreg.org/about-us/working-with-us/
3. Data are made available to researchers promptly after completion of the approved process including peer review and completion of data sharing agreement as outlined on the UKRR website

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/04/2017	07/01/2022	Yes	No
Interim results article		09/01/2017	07/01/2022	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes