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The Acute Care QUAliTy in chronIc Kidney disease study

Submission date
21/11/2013

Recruitment status
No longer recruiting

Registration date
05/02/2014

Overall study status
Completed

Last Edited
04/11/2020

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
Studies, mainly from America, have suggested that patients whose kidneys do not work properly are more likely to be readmitted to hospital due to a long-term condition called chronic kidney disease. This is a study of patients admitted to hospitals in Birmingham (UK) to see if this is the case in the UK. The study also looks at other factors such as age and race to see if these affect the results. These findings should help improve the treatment that patients with chronic kidney disease get before and after being admitted to hospital.

Who can participate?
Adult men and women admitted to hospitals in Birmingham with and without chronic kidney disease

What does the study involve?
Over a period of two years patients are invited to participate in this study during an admission to hospital. At recruitment, participants are asked a few lifestyle questions. They are then followed up using existing electronic databases for a minimum of 2 years and a maximum of 4 years.

What are the possible benefits and risks of participating?
There is no immediate direct benefit to those taking part but there should be benefits to future patients who are admitted to hospital so that we will be better able to understand reasons for readmission.

Where is the study run from?
University Hospital Birmingham (UK)

When is study starting and how long is it expected to run for?
September 2013 to October 2015

Who is funding the study?
The National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
Dr Charles Ferro

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RRK4784

Study information

Scientific Title
The Acute Care QUAliTy in chronIc Kidney disease study: an observational cohort study

Acronym
ACQUATIK

Study objectives
The principal objective is to identify whether a diagnosis of chronic kidney disease influences the treatment and long-term outcomes of patients admitted to hospital. This is the primary end-point of the study on which the sample size calculation is based.

Do UK patients classified with chronic kidney disease (CKD) by their GP have higher hospital re-admission rates than patients not classified with CKD?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - South Birmingham, ref: 13/WM/0317

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
This will be a multi-centre, observational, prospective, longitudinal study of approximately 4000 patients to be recruited over two years.

Two core centres in Birmingham (University Hospital Birmingham NHS Foundation Trust; Heart of England Foundation Trust), with a high number of acute admissions and serving a large ethnically diverse population are undertaking this observational study. Additional centres may join to help contribute to the recruitment of patients.

Patients will be approached by members of the clinical research after having been identified by a member of their clinical team. Where possible, an introduction will be made by a member of the clinical team responsible for the potential participants' care.

The patient will be given a verbal explanation of the study and given a written information sheet. They will be given sufficient time to ask questions and think about their potential participation. If necessary a member of the research team will return the following day if the potential participant wants more time to discuss their participation with family and friends.

Once they have given consent that will be the end of the participants' direct involvement in the research other than to receive updates of the study progress or if they wish to withdraw. At the time of consent a simple form will be filled in consisting of their NHS/Unit number and admission date. That information will then be passed on to the Department of Medical Informatics at the University Hospital Birmingham NHS Foundation Trust. Data held by the participants' general practitioner on their medication and chronic conditions will then be extracted and entered into a secure research database after having been pseudo-anonymised. This baseline data will then be

linked via a unique identifier number to obtain detailed information on current and future hospital admissions as well as death from the Hospital Episode Statistics and the Office of National Statistics.

Patient enrolment period will be 2 years. Participants will be followed up for a minimum period of 2 years (last patient enrolled) and up to a maximum of 4 years (first patient enrolled).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Do UK patients classified with chronic kidney disease by their GP have higher hospital re-admission rates than patients not classified with CKD

Secondary outcome measures
1. Do UK patients classified as having CKD by their GP have higher hospital re-admission rates for a cardiovascular disease event (i.e., hospitalization for acute myocardial infarction, angina, coronary artery bypass graft surgery, percutaneous coronary intervention, peripheral arterial disease, revascularization or stroke) than patients not classified with CKD
2. Do UK patients classified as having CKD by their GP have higher all-cause and cardiovascular mortality than patients not classified with CKD
3. Do UK patients classified as having CKD by their GP receive the same primary and secondary prevention treatments for cardiovascular disease as do patients not classified with CKD
4. Do UK patients classified as having CKD by their GP attain the same targets in the management of chronic diseases as defined by the QOF compared with patients not classified as having CKD
5. Do UK patients classified as having CKD by their GP receive the same treatment for cardiovascular disease when admitted to hospital with a cardiovascular event
6. Do UK patients classified with CKD by their GP derive the same benefit:risk ratio from primary and secondary prevention treatments for cardiovascular disease as do patients not classified with CKD
7. Do UK patients classified with CKD by their GP have a higher risk of further deterioration in renal function (acute kidney injury) than patients not classified with CKD
8. Are there a significant number of patients with biochemical evidence of CKD not classified as such by their GP

In addition, there will be a number of secondary analyses performed. All of the above research questions will be analysed separately to investigate the influence of age, ethnicity, SES, deprivation score, gender and concurrent co-morbidities on outcomes, treatment and classifications.

Overall study start date
30/09/2013

Completion date
01/10/2015

Eligibility

Key inclusion criteria
1. Male and female aged 18 years or over
2. Patient from GP practices in the two main Clinical Commissioning Groups served by University Hospital Birmingham NHS Foundation Trust and Heart of England NHS Foundation Trust; i.e. Birmingham South and Central and Birmingham Cross City CCGs

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
4000

Key exclusion criteria
1. Unable to give informed consent
2. Patient on dialysis or with a working kidney transplant
3. Patient already under long-term follow-up by renal team in secondary care

Date of first enrolment
30/09/2013

Date of final enrolment
01/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Birmingham
United Kingdom
B15 2WB

Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust (UK)

Sponsor details
Research and Development Department
Edgbaston
Birmingham
England
United Kingdom
B15 2TH

Sponsor type
Hospital/treatment centre

Website
http://www.uhb.nhs.uk/

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Post Doctoral Fellowship ref: NIHR-PDF-2012-05-205

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/05/2015		Yes	No
HRA research summary			28/06/2023	No	No