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Palliative care in chronic kidney disease study (PACKS study)

Submission date
14/04/2014

Recruitment status
No longer recruiting

Registration date
01/07/2014

Overall study status
Completed

Last Edited
11/12/2018

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
The kidneys main function is to filter the waste products that build up in our bodies and convert them into urine. Chronic kidney disease is a long term condition where the kidneys do not work properly. Symptoms include feeling tired, water retention (leading to swollen ankles, feet or hands), shortness of breath, feeling sick and passing blood in the urine. There is no cure for the condition, but it can be managed through changes in lifestyle and taking medications. Eventually, chronic kidney disease can lead to kidney failure, a stage where the organ has almost completely stopped functioning. This is life threatening and patients are faced with several treatment options including dialysis, kidney transplant, or palliative care. This study will examine the quality of life (QOL), decision making, costs and mortality in patients with advanced chronic kidney disease who have opted for palliative care. It will also explore care decisions made by patient carers from the perspective of the patient, care and health care professionals and the impact on the QOL of carers.

Who can participate?
1. Adult patients with end stage (stage 5) chronic kidney disease who have opted for palliative care.
2. Adult carers of a patient with end stage chronic kidney disease who have opted for palliative care.
3. Renal physicians/Clinical Nurse Specialists (CNS) who have experience of treating patients with end stage chronic kidney disease who have opted for palliative care.

What does the study involve?
Over a period of one year participants will be invited to answer questionnaires every 3 months. The questionnaires, some for patients and some for carers, will explore QOL, symptoms, decision making and impact on carers. Patients will also be asked to complete a log of health and social care use e.g. how often they visited their GP. Renal physicians/CNSs will be asked to participate in an interview to explore the decision making process that precedes referral to conservative kidney management in relation to patient satisfaction in decision making. We will also explore cognition (ability to think clearly), frailty and performance. At the end of the study,

we will have a better understanding of the impact a non-dialysis approach has on QOL, range and severity of symptoms, cognition (ability to think clearly), frailty, performance, costs and the impact on carers.

What are the possible benefits and risks of participating?
The study is unlikely to help participants directly but the information we get might help improve the treatment of people with advanced chronic kidney disease who opt for palliative care in the future. Risks to participants are minimal but the information shared may be sensitive and cause upset. If this happens support will be available from a Renal Counsellor or nursing staff with counselling skills.

Where is the study run from?
10 NHS hospital trusts across the UK.

When is the study starting and how long is it expected to run for?
July 2014 to December 2016

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CDV/4872/13

Study information

Scientific Title
PAlliative Care in chronic Kidney diSease study (PACKS) Study: Quality of life, decision making, costs and impact on carers in people managed without dialysis

Acronym
PACKS

Study objectives
The aim of the study is to measure and describe longitudinally QOL, satisfaction with decision-making, costs, cognition, frailty and performance in patients with advanced chronic kidney disease managed without dialysis. The impact on carers will also be studied.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees Northern Ireland (ORECNI), 14/05/2014, ref. 14/NI/0057

Study design
Multiple method study to include quantitative and qualitative components

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Advanced chronic kidney disease

Interventions
Current interventions as of 04/02/2015:
This is a multiple method study which includes quantitative and qualitative components. In the quantitative component longitudinal survey of quality of life (QOL), symptoms, cognition, frailty and performance will be measured 3-monthly and satisfaction in decision-making 6-monthly. Health and social care costs will be captured over the duration of the study using patient logs. QOL in carers and associated costs will be explored. Carer observation of patient's satisfaction in decision making will be collected 6-monthly and carer assessment of patient QOL by proxy 3-monthly over 12 months. In the qualitative component of the study, the decision-making process that precedes referral to conservative kidney management in relation to patient satisfaction in decision making will be explored with renal physicians/clinical nurse specialists (CNS) via semi-structured interviews. Some people may change their mind regarding their selected treatment option and commence dialysis, although this is unusual in clinical practice. If this happens the patient and carer data will continue to be collected in order to examine how QOL might increase /decrease with a switch of modality.

The study takes place in the UK across 10 sites in the UK; five in Northern Ireland and up to five in London. Each site offers the option of conservative management as a treatment option to patients who have reached end-stage renal disease. All patients who make the decision not to embark on dialysis will be approached to take part in the study. Their main carer will be approached only with the patient's consent.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measures as of 04/02/2015:
Quality of life (QOL) of patients at 3 months measured using the EQ-VAS.

Previous primary outcome measures:
Quality of life (QOL) of patients at 3 months measured using the EQ-5D-5L visual analogue scale.

Key secondary outcome(s))
Current secondary outcome measures as of 04/02/2015:
Patients
1. Changes in QOL, symptoms, anxiety and depression in patients using the Kidney Disease QOL (KDQOL) tool, EQ-5D-5L (which includes the EQ-VAS) and Palliative Outcome Scale - Symptoms (POS-S) Renal 3-monthly up to 12 months
2. Changes in cognition and frailty status in patients using the 6-Item Cognitive Impairment Test (6CIT) and the 9-point Clinical Frailty Scale 3-monthly up to 12 months
3. Changes in Performance in patients using the Palliative Performance Scale (PPS) 3-monthly up to 12 months
4. Patient Satisfaction in Decision Making using the Decisional Conflict Scale (DCS) at baseline
5. Measurement of health and social care costs of patients receiving conservative kidney management using a Patient Service Use Log 3-monthly up to 12 months
6. Calculation of the number (%) of patient deaths 3-monthly and time to death

Carers
1. Carer observation of patient's Satisfaction in Decision Making using the Decisional Conflict Scale (DCS) at baseline and 6-monthly where possible
2. Changes in QOL of carers using the EQ-5D-5L 3-monthly over 12 months
3. Carer's assessment of patient QOL using the EQ-5D-5L by proxy 3-monthly over 12 months
4. Subjective and objective burden of providing informal care in carers, loss of earnings and the opportunity costs of providing informal care using items from the iMTA Valuation of Informal Care Questionnaire (iVICQ; Hoefman et al 2011) 3 monthly over the 12 months.

Renal Physicians/Clinical Nurse Specialists
1. Exploration of the decision-making process that precedes referral to conservative kidney management in relation to patient satisfaction with renal physicians/CNS via exploratory qualitative interviews.

Previous secondary outcome measures:
1. Changes in QOL, symptoms, anxiety and depression in patients using the Kidney Disease QOL (KDQOL) tool, EQ-5D-5L and Palliative Outcome Scale - Symptoms (POS-S) Renal, 3-monthly over 12 months
2. Changes in cognition and frailty status using the 6 Item Cognitive Impairment Test (6CIT) and the 9-point Clinical Frailty Scale (CFS) 3-monthly over 12 months
3. Changes in performance using the Palliative Performance Scale (PPS) 3-monthly over 12 months
4. Patient satisfaction in decision making using the Decisional Conflict Scale (DCS) at baseline
5. Carer observation of patient's satisfaction in decision making using the Decisional Conflict Scale (DCS) at baseline
6. Identification of health and social care costs of patients receiving conservative kidney

management using a patient service use log over 12 months of study
7. Changes in QOL for carers using the EQ-5D-5L visual analogue scale 3-monthly over 12 months
8. Carers assessment of patient QOL using the EQ-5D-5L by proxy 3-monthly over 12 months
9. Identification of costs to carers of patients receiving conservative kidney management using a carer questionnaire at baseline and another at 3, 6, 9 and 12 months of study
10. Exploration of decision making process that precedes referral to conservative kidney management with renal physicians/CNS via exploratory qualitative interviews
11. Calculation of the number (%) of deaths at 3, 6, 9 and 12 months and time to death

Completion date
09/12/2016

Eligibility

Key inclusion criteria
Patients:
1. Stage 5 chronic kidney disease with estimated glomerular filtration rate ≤ 20 mL/minute as measured by the Modification of Diet in Renal Disease (MDRD) formula (Levey et al 1999)
2. A confirmed decision for conservative management, i.e. management without dialysis or other renal replacement therapy. The decision for conservative kidney management will be confirmed with the nephrologist responsible for each patient.
3. Aged over 18 years

Carers:
1. Primary carer for patient with stage 5 chronic kidney disease who has made a confirmed decision for conservative kidney management as agreed with clinicians
2. Aged over 18 years
3. Patient has agreed that the carer can be approached to participate
4. The carer has contacted staff and 'opted in' to the study (added 04/02/2015)

Renal physicians/CNS:
1. Experience of managing clinical consultations of patients with stage 5 chronic kidney disease who opt for conservative kidney management
2. Employed in the renal specialty

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

Patients:
1. Patients lacking capacity to give consent to participate. Capacity for consent to participate will be assessed in collaboration with the clinicians.
2. Stage 1-4 chronic kidney disease
3. Hasn't made a confirmed decision for conservative management
4. Under the age of 18
5. Non-English speaking patients or those who do not adequately understand verbal or written information unless an interpreter is available

Carers:
1. Carers who lack capacity to give consent to participate in the study
2. Under the age of 18
3. Patient has not agreed that the carer can be approached to participate
4. Non-English speaking patients or those who do not adequately understand verbal or written information unless an interpreter is available
5. Carer has not contacted staff and 'opted in' to the study (added 04/02/2015)

Renal physicians/CNS:
1. No experience of managing clinical consultations of patients who opt for conservative kidney management
2. Not employed in the renal specialty

Date of first enrolment
01/02/2015

Date of final enrolment
31/05/2016

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Belfast Health & Social Care Trust
Belfast
United Kingdom
-

Study participating centre
Northern Health & Social Care Trust
United Kingdom
-

Study participating centre
Southern Health & Social Care Trust
United Kingdom
-

Study participating centre
Western Health & Social Care Trust
United Kingdom
-

Study participating centre
South Eastern Health & Social Care Trust
United Kingdom
-

Study participating centre
Barts Health NHS Trust
United Kingdom
-

Study participating centre
The Royal Free London NHS Foundation Trust
United Kingdom
-

Study participating centre
St George's University Hospitals NHS Foundation Trust
United Kingdom
-

Study participating centre
South Glasgow University Hospital
NHS Greater Glasgow & Clyde
1345 Govan Road
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United Kingdom
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Study participating centre
The Lister Hospital
East and North Hertfordshire NHS Trust
Chelsea Bridge Road
London
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Sponsor information

Organisation
Queen's University of Belfast (UK)

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK); ref. CDV/4872/13

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
Results article	results	01/12/2017		Yes	No
Results article	results	01/09/2018		Yes	No
Protocol article	protocol	11/07/2015		Yes	No
HRA research summary			28/06/2023	No	No