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Pilot study to review alternative assessments of adequacy of dialysis in patients with kidney failure

Submission date
11/10/2013

Recruitment status
No longer recruiting

Registration date
01/11/2013

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
The dose or adequacy of dialysis treatments (removal of waste from the body) for kidney failure patients is currently assessed by the removal of urea, a waste product of protein turnover. However, simply changing dialysis treatments to increase the amount of urea removed has not been shown to increase patient survival. Cardiac disease is the most common cause of death in kidney failure patients, and additional risk factors for cardiac death have been reported for these patients. Newer treatment methods that can reduce these risk factors are necessary. The main aim of this study is to measure three key risk factors associated with increased risk of death in different groups of kidney failure patients. Another aim is to find out whether any of the current treatments for kidney failure reduce these risk factors. Information from this initial study would then hopefully be used for future research.

Who can participate?
Patients with long-term kidney disease who are treated by outpatient dialysis

What does the study involve ?
Skin auto fluorescence is measured using a non-invasive technique that shines a light onto the forearm skin and measures the reflection. This can be done when patients are sitting or lying down whilst having dialysis. In addition to the usual tests that are done during their routine medical care 10 ml of blood is taken when the patients are having their routine blood testing. If patients have not had a recent electrical recording of the heart (ECG) as part of their normal routine care (performed annually) an ECG is recorded to look at the variability in heart beats. The relationship between these risk factors and heart disease is assessed. Blood pressure is also measured using a standard blood pressure cuff placed on the arm, and the recording is used to find out the stiffness of the arteries and also measure the thickness of the artery at the wrist or foot using ultrasound. This is a non-invasive technique and can be performed as the patient has their dialysis treatment.

What are the possible benefits and risks of participating?
There may be no immediate benefits to any patient. However, if any of the tests performed

show significant risk factors for heart disease, these will be made available to their supervising kidney consultant who may then make changes to their treatment. Apart from an additional blood test, all other tests are non-invasive and painless and can be performed whilst patients are having dialysis.

Where is the study run from?
Royal Free Hospital (UK)

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

Who is funding the study?
Royal Free Hospital (UK)

Who is the main contact?
Dr Andrew Davenport
andrewdavenport@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Andrew Davenport

Contact details
UCL Centre for Nephrology
Royal Free Hospital
London
United Kingdom
NW3 2QG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol version 1.1

Study information

Scientific Title
Pilot study to review alternative assessments of adequacy of dialysis in patients with kidney failure: a prospective cohort study

Study objectives
Currently the amount of dialysis treatment given to patients with chronic kidney disease is based on the amount of urea removed during a dialysis session. Using this guideline for dosing dialysis, in the UK the 5-year survival of kidney dialysis patients is marginally better than that for ovarian cancer, and worse than that of bowel cancer. The trialists hypothesise that newer targets for treating kidney dialysis patients are required to improve survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Camden & Islington, September 2013, REC ref: 13/LO/0912, IRAS project ID: 129559

Study design
Prospective cohort study

Primary study design
Interventional

Secondary study design
Non randomised 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
Renal and cardiac

Interventions
Conventional markers of dialysis adequacy and in addition measurement of skin autofluorescence, plasma endotoxin and modified albumin.
Cardiovascular assessments: blood pressure (pulse wave velocity), ECG (with analysis for autonomic dysfunction), and measurement of diameter of radial or dorsalis pedis artery.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

To determine the practicability of measuring skin autofluorescence, endotoxin and modified albumin in the study population and whether these factors correlate with conventional markers of dialysis adequacy.

Blood samples will be taken at entry into the study and then at 12 months to determine concentrations of endotoxin and modified albumin. Similarly blood pressure, ECG and skin autofluorescence will be measured at study entry and then at 12 months. Measurements of arterial size will be made once at study entry.

Secondary outcome measures
To determine whether skin autofluorescence, endotoxin and modified albumin correlate with cardiovascular risk factors

Overall study start date
01/10/2013

Completion date
31/10/2015

Eligibility

Key inclusion criteria
1. Treated for chronic kidney failure
2. Ability to provide informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
More than 100

Key exclusion criteria
1. Unable to provide informed consent
2. Aged below 18 years

Date of first enrolment
01/10/2013

Date of final enrolment
31/10/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Royal Free Hospital
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
Royal Free Hospital (UK)

Sponsor details
Pond street
London
England
United Kingdom
NW3 2QG

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ge67z96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Free Hospital (UK)

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?
Results article	results	14/04/2015	17/12/2020	Yes	No
HRA research summary			28/06/2023	No	No