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Calcium balance during haemodiafiltration and high flux haemodialysis

Submission date	Recruitment status	[_] Prospectively registered
11/10/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/11/2013	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
01/11/2013	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
During haemodialysis (removal of waste from the blood) blood flows out from the patient into the dialyzer. Substances move by diffusion from the blood into the dialysate (one of the two solutions used in dialysis), or vice-versa. Dialysis is not a selective process and substances in the dialysate can equally pass into the patients blood if in higher concentration. Haemodialysis patients are at increased risk of hardening (calcification) of soft tissues, especially calcification of blood vessels. This leads to reduced blood supply to the skin and feet and an increased risk of calcium deposits leading to skin ulceration and amputation. Intake of calcium in the form of calcium-containing medications increases the risk of calcification. However, dialysis patients get calcium from the dialysate which can directly pass into their blood. Although the amounts of calcium transferred during a single session may be small, repeating this three times a week, year after year can result in a large amount of calcium infused and so increase the risk of calcification of blood vessels. Unfortunately there is no information on the amount of calcium gained or lost during haemodialysis or a newer dialysis treatment (haemodiafiltration), and no evidence-based guidelines as how to choose a dialysate calcium concentration for patients. We will measure how much calcium has been gained or lost during dialysis, using dialysis fluids containing different amounts of calcium. This study will allow the development of evidence-based guidelines to help doctors decide on what dialysate calcium concentration to use to reduce calcium loading and vascular calcification.

Who can participate?
Patients with long-term kidney disease who are treated by outpatient haemodialysis can participate in this study.

What does the study involve?
One of three different commercially available dialysate calcium concentrations will be chosen. All patients will initially receive their standard dialysis. An electronic recording of the heart (ECG) will be made at the start and end of the dialysis session. After completing the sequence of dialysis sessions, patients would then have two additional dialysis sessions, one each of haemodiafiltration and haemodialysis, using a different calcium concentration. Each session would be one week apart. We will do blood tests both at the start and the end of the dialysis session.

What are the possible benefits and risks of participating?
At the end of the study the information obtained will be given to the patients consultant who can then choose the correct calcium concentration in the dialysis fluid. All three dialysis calcium concentrations in dialysis fluid are in routine clinical use and do not pose a health risk. As an additional safety measure we will check your ECG prior to the dialysis treatment, and your blood test at the start and end of the dialysis session.

Where is the study run from?
The study is run from the UCL Centre for Nephrology at the Royal Free Hospital, UK.

When is study starting and how long is it expected to run for?
It starts in October 2013 and depending upon recruitment is expected to last for three years.

Who is funding the study?
The study is funded by the 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
Study to investigate calcium balance during haemodiafiltration and high flux haemodialysis

Study objectives
Dialysis patients are at increased risk of vascular calcification. We wish to determine whether the mode of dialysis affects calcium influx or loss during a dialysis treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Central; date: 03/04/2013; REC reference:13/LO/0384; IRAS project ID:118378

Study design
Cross over cohort study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Renal

Interventions
1. ECG
2. Measurement of pre and post dialysis biochemistry including ionised serum calcium and dialysate biochemistries during haemodialysis and haemodiafiltration treatments

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To determine whether there is a difference in calcium balance between haemodialysis and haemodiafiltration treatments. Calcium balance will be measured by comparing the amount of calcium delivered in the dialysate and that recovered in the spent dialysate, and the calcium flux (difference between the two) compared to measurements of calcium, and other electrolytes in blood tests at the start and end of calcium and parathyroid hormone concentrations.

Secondary outcome measures
Sodium and other electrolyte balance, changes in blood pressure and fluid removal and ECG changes

Overall study start date
20/10/2013

Completion date
30/10/2016

Eligibility

Key inclusion criteria
1. Thrice weekly haemodialysis or haemodiafiltration
2. Ability to provide informed consent
3. Serum total calcium within laboratory normal reference range
4. Reliably functioning vascular access for dialysis

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
10-15

Key exclusion criteria
1. Unable to provide informed consent
2. Aged 18 to 85 years
3. ECG with prolonged QTc
4. History of life-threatening cardiac arrhythmias
5. Recent myocardial infarction within previous 3 months
6. Admission to hospital for change in vascular access
7. Unlikely to survive 6 months
8. Planned living donor transplant
9. Patients with history of missing dialysis sessions

Date of first enrolment
20/10/2013

Date of final enrolment
30/10/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UCL Centre for Nephrology
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?
HRA research summary			28/06/2023	No	No