ISRCTN12870218 https://doi.org/10.1186/ISRCTN12870218

To determine whether changes in pulse wave velocity predict hypotension during dialysis

Submission date
11/10/2013

Recruitment status
No longer recruiting

Registration date
01/11/2013

Overall study status
Completed

Last Edited
17/01/2017

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Low blood pressure is the most common complication for patients attending for routine outpatient haemodialysis treatments (filtering out waste products from the blood). Low blood pressure could be due to too low a blood volume, but could also be due to relaxation of the blood vessels. We wish to measure blood pressure during dialysis with a more sophisticated blood pressure machine that provides information about the stiffness of the major arteries to see whether there is relaxation of these arteries occurring before a fall in blood pressure.

Who can participate?
Patients with long-term kidney disease who are treated by regular outpatient haemodialysis in the Royal Free Hospital can participate in the study.

What does the study involve ?
When patients come for haemodialysis we will use a standard blood pressure cuff placed on the upper arm which is linked to a blood pressure machine and a computer that can measure pulse wave velocity. This equipment is currently used in routine clinical practice. The only difference compared to a standard blood pressure machine is that the blood pressure cuff inflates three times. As with standard practice, blood pressure will be measured before dialysis, at 20 minutes, then hourly. If you have not had a recent electrical recording of the heart (ECG) we will perform one.

What are the possible benefits and risks of participating?
There may be no immediate benefits to any patient. No additional blood tests are required, and the blood pressure test is non-invasive and does not cause pain and is performed whilst patients are having dialysis. Similarly if an ECG is recorded, this is painless and can be done during the dialysis treatment.

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?
The study starts in January 2013 is expected to end in late 2014.

Who is funding the study?
The study is funded by the Royal Free Hospital, UK.

Who is the main contact?
Dr Andrew Davenport
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Contact information

Type(s)
Scientific

Contact name
Dr Andrew Davenport

Contact details
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Royal Free Hospital
Pond St
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
protocol version 4

Study information

Scientific Title
Study to determine whether changes in pulse wave velocity are associated with changes in blood pressure in haemodialysis patients

Study objectives
Do changes in major arterial compliance occur during haemodialysis and does this lead to low blood pressure during haemodialysis?

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Central Ethics Committee, 05/09/2012, ref: 12/LO/0976

Study design
Prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files

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

Interventions
All participants have a blood pressure cuff placed around their non fistula arm. Blood pressure measurements are taken three times spaced three minutes apart, during which time pulse wave velocity measurements are taken.
Post-dialysis, medical records are reviewed to see if there is any relationship to the changes of blood pressure during dialysis.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Blood pressure and pulse wave velocity are measured using a blood pressure cuff.
Blood pressure will be measured at the start of a dialysis session, then at 20 minutes, one hour and then hourly during the dialysis session. Changes in pulse wave velocity and heartbeat variation will be reviewed to determine whether these are related to changes in blood pressure during the dialysis session.

Secondary outcome measures
Derived variables from pulse wave velocity.

Overall study start date
01/01/2013

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Patients with chronic kidney disease treated by haemodialysis
2. Patients who are able to provide valid consent
3. Patients who can have their blood pressure measured using an arm blood pressure cuff

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
More than 100

Key exclusion criteria
1. Patients who do not fulfil the inclusion criteria
2. Patients who cannot provide valid informed consent
3. Patients who cannot have their blood pressure measured using an upper arm blood pressure cuff
4. Those with atrial fibrillation and other cardiac arrhythmias

Date of first enrolment
01/01/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UCL Centre for Nephrology
Royal Free Hospital
Pond St
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
Royal Free Hospital (UK)

Sponsor details
Pond street
London
England
United Kingdom
NW32QG

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
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2013

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	08/09/2013		Yes	No

Participant information sheet	version V4	09/08/2012	17/01/2017	No	Yes