

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

Submission date 11/10/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/11/2013	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/01/2017	Condition category Circulatory System	☐ 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
UCL Centre for Nephrology
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NW3 2QG

Additional identifiers

Protocol serial number
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

Primary study design
Observational

Study design
Prospective cohort study

Study type(s)

Diagnostic

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(s)

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.

Key secondary outcome(s)

Derived variables from pulse wave velocity.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

UCL Centre for Nephrology

Royal Free Hospital

Pond St

London

United Kingdom

NW3 2QG

Sponsor information**Organisation**

Royal Free Hospital (UK)

ROR

<https://ror.org/01ge67z96>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Royal Free Hospital (UK)

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	08/09/2013		Yes	No
Participant information sheet	version V4	09/08/2012	17/01/2017	No	Yes