

Can changes in dialysis treatment decrease substances which are related to ageing

Submission date 13/11/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/11/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/01/2017	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Background and study aims

In a healthy person, the kidneys are responsible for filtering out the waste products and excess water in the blood, and converting them into urine. When the kidneys fail, they stop cleaning the blood, leading to the build-up of harmful waste products. Dialysis is a common treatment for kidney disease, where harmful waste products and excess fluid are removed from the body, usually by diverting a patient's blood through a special filtering machine, which uses a solution called dialysate to draw waste products out of the blood to 'clean' it. Advanced glycation end products (AGE) are a family of waste products which are formed by reactions with sugar breakdown products (glucose metabolites). In patients undergoing dialysis treatment, AGE often accumulate, and build up in connective tissues, for example in the collagen of the skin. Some AGE are visible if UV light is shone on them through a device called an AGE-reader (skin autofluorescence). The aim of this study is to compare the skin autofluorescence in dialysis patients when a dialysate containing glucose and one containing no glucose is used.

Who can participate?

Adults who are on long term dialysis treatment at the dialysis unit at Norrlands University Hospital, Umeå, Sweden.

What does the study involve?

At the start of the study, participants have their skin autofluorescence measured using a special machine called an AGE reader. This involves placing the forearm onto the machine which then shines light through the arm to measure the amount of light that is absorbed. The amount of AGE present in the skin can then be calculated. Participants then continue to receive dialysis using their usual glucose-containing dialysate for four weeks. Participants are then switched to a glucose-free dialysate. After the third and sixth dialysis session using the new dialysate (one and two weeks after the switch), the skin autofluorescence test is repeated.

What are the possible benefits and risks of participating?

There are no direct benefits or risks involved with participating.

Where is the study run from?

Norrland University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
January 2007 to May 2009

Who is funding the study?

1. Västerbotten Läns Landsting (Sweden)
2. Norrlands Kidney Patient Association (Sweden)

Who is the main contact?

Professor Bernd Stegmayr
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

1

Study information

Scientific Title

Measuring skin- and plasmaautofluorescence in hemodialysis patients either with glucose free or glucose-containing dialysate

Study objectives

The aim of this study is to investigate if there is a difference between the use of a dialysate not containing glucose compared with a glucose containing dialysate

Ethics approval required

Old ethics approval format

Ethics approval(s)

Study design

Non-randomised study

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Cardiovascular disease in hemodialysis patients

Interventions

Patients on chronic hemodialysis with glucose containing dialysis bath (concentration 5 mmol/L) continue their usual treatment for the initial four weeks of the study. Following this, the dialysis concentrate is switched to glucose free dialysate. The dialysis procedure does not differ by using a different dialysis concentrate.

At baseline and then one and two weeks after the dialysate switch (after the third and after the sixth dialysis treatment with glucose free dialysate), participants have their skin autofluorescence measured using anAGE Reader and their plasma autofluorescence measured using a Tecan Genios microplate reader.

Following the final measurement, the dialysate is changed back to the dialysate the participants were using prior to the study.

Intervention Type

Other

Primary outcome(s)

Skin autofluorescence is measured using the AGE Reader (DiagnOptics Technologies BV, Groningen, The Netherlands) at baseline, 1 and 2 weeks after dialysate is switched to glucose free dialysate.

Key secondary outcome(s)

Plasma autofluorescence is measured using a Tecan Genios microplate reader (Tecan Group Ltd., Männedorf, Switzerland) at baseline, 1 and 2 weeks after dialysate is switched to glucose free dialysate.

Completion date

11/05/2009

Eligibility**Key inclusion criteria**

1. Adult patients (age > 18 years), no upper limit of age
2. Chronic dialysis treatment (patients with dialysis treatment more than three months)
3. All patients treated at the dialysis unit at Norrlands university hospital, Umeå, Sweden, who give informed consent and have no exclusion criterias

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Ongoing infection (elevated CRP)
2. Inability to understand information and give informed consent
3. Patients with diabetes mellitus prone to hypoglycemia

Date of first enrolment

31/03/2009

Date of final enrolment

01/04/2009

Locations**Countries of recruitment**

Sweden

Study participating centre

Norrland University Hospital

Universitetssjukhuset

Umeå

Sweden

90185

Sponsor information

Organisation

Norrlands University Hospital

ROR

<https://ror.org/012k96e85>

Funder(s)

Funder type

Government

Funder Name

Västerbotten Läns Landsting

Alternative Name(s)

Västerbotten County Council

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Funder Name

Norrlands Kidney Patient Association

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Bernd Stegmayr (bernd.stegmayr@umu.se) and Bernd Ramsauer (bernd.ramsauer@vgregion.se)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/01/2017		Yes	No

