ISRCTN13837553 https://doi.org/10.1186/ISRCTN13837553

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

Submission date
13/11/2016

Recruitment status
No longer recruiting

Registration date
16/11/2016

Overall study status
Completed

Last Edited
09/01/2017

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
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 autoflourescence). The aim of this study is to compare the skin autoflourescence 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 autoflourescence 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 autoflourescence test is repeated.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involve 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 the 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)
The Regional Ethical Review Board in Umeå. Dept. of Medical Research, 12/03/2008, ref: Dnr 08-023M

Study design
Non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular disease in hemodialysis patients

Interventions
Patients on chronic hemodialysis with glucose containing dialysis bath (contentration 5 mmol/L) continue their usual treatement 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 uisng 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 measure
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.

Secondary outcome measures

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.

Overall study start date
21/01/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

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

Sponsor details
Dept. of Nephrology
Dialysis unit
Universitetssjukhuset
Umeå
Sweden
90185

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/03/2017

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