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Effect of different dialysis modalities on serum hepcidin, the key regulator of iron metabolism

Submission date
30/08/2015

Recruitment status
No longer recruiting

Registration date
12/10/2015

Overall study status
Completed

Last Edited
17/01/2020

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Chronic kidney disease (CKD) is a long-term condition where the kidneys do not work properly. In a healthy person, the kidneys are vital for filtering out the waste products and excess water in the blood, and converting them into urine. In patients suffering from CKD, the kidneys are unable to do this, and so the body is unable to get rid of the waste products building up in the blood. Hemodialysis is one of the most common treatments for CKD patients, and involves diverting the blood into an external machine so that it can be “cleaned”, before being returned to the body. It has been found that patients who are being treated with hemodialysis have higher levels of the hormone hepcidin-25 (Hep-25) in the blood than normal. This hormone is vital for regulating the amount of iron in the body, and high levels can lead to too not enough iron being absorbed by the intestines. It is thought that the high levels of Hep-25 are caused by the hemodialysis treatment itself, as it triggers inflammation. Hemodiafiltration reinfusion (HFR) is a type of dialysis which reduces inflammation. The aim of this study is to compare the amount of Hep-25 and other chemical markers of inflammation (inflammatory biomarkers) in hemodiafiltration reinfusion (HFR) and standard bicarbonate dialysis (usual practice).

Who can participate?
Adults who have been attending the unit for hemodialysis treatment for more than three months by the study start date.

What does the study involve?
All patients receive each of the treatments. The order that the treatments are received is decided using a coin toss. Before and after each treatment, the amount of Hep-25 and the inflammatory biomarkers in the blood are measured.

What are the possible benefits and risks of participating?
Participants may benefit from being able to find a better hemodialysis technique to reduce their blood levels of hepcidin. There are no risks of participating, as both techniques are used in general practice.

Where is the study run from?
Nephrology and Dialysis Unit, Azienda Ospedaliera Universitaria Integrata Verona (Italy)

When is the study starting and how long is it expected to run for?
June 2009 to October 2009

Who is funding the study?
Nephrology and Dialysis Unit, Azienda Ospedaliera Universitaria Integrata Verona (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect on serum hepcidin-25 levels of a single hemodialysis session with hemodiafiltration with sorbent-regenerated endogenous ultrafiltrate reinfusion (HFR) by comparison with bicarbonate dialysis: A crossover study

Study objectives

The haemodialysis procedure itself can influence Hep-25 levels by removing hepcidin and/or stimulating its production due to a pro-inflammatory effect.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Clinical Research of the provinces of Verona and Rovigo (Comitato Etico per la Sperimentazione Clinica delle provincie di Verona e Rovigo), 22/08/2007, ref: 1460

Study design
Single-centre randomized cross-over interventional trial.

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic kidney disease

Interventions
In all enrolled patients we tested the effect on serum hepcidin-25 and on serum levels of a panel of biomarkers of inflammation (TNF-alfa, IL-6, Pentraxin3 and C reactive protein) of single session of HFR and standard bicarbonate-dialysis using the same low-flux membrane used in the diffusive stage of HFR (to assess the relative contribution of the convective/adsorptive and the diffusive stages of the HFR technique). The order that patients received the treatments has been determined using a coin toss. In a subset of 18 patients we also evaluated the effect of a single session of bicarbonate-dialysis using a high-flux membrane.

Intervention Type
Device

Primary outcome measure
Reduction Ratios (RR) of hepcidin and the inflammatory biomarkers (IL-6, TNF-a, Pentraxin 3 and C-reactive protein) are calculated using the formula RR = (Cpre - Cpost/Cpre) x 100 (where Cpre is the concentration just before dialysis and Cpost the concentration at the end of dialysis).

Secondary outcome measures
Blood-side clearance of hepcidin and the inflammatory biomarkers (IL-6, TNF-a, Pentraxin 3 and C-reactive protein) calculated 90 minutes after the dialysis starts. Blood samples for the assays

were taken from the dialyzer inlet and outlet:. K was calculated by the formula K= Qb x (Cbi – Cbo / Cbi), where Qb is the blood flow rate, Cbi is the solute serum levels at the dialyzer inlet, and Cbo the solute serum levels at the dialyzer outlet.

Overall study start date
02/03/2009

Completion date
10/01/2015

Eligibility

Key inclusion criteria
1. Aged over 18 years.
2. Chronic hemodialysys patients on erytrhopoiesis-stimulating agents
3. Have been attending the unit for dialysis for more than 3 months by June 2009
4. Have participated in the previous study (protocol # 1460)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
19

Key exclusion criteria
1. Liver cirrhosis
2. Neoplasia
3. Chronic Inflammatory disorder
4. Acute inflammatory disease
5. Solid organ transplantation
6. No informed consent to trial # 1460

Date of first enrolment
01/06/2009

Date of final enrolment
30/10/2009

Locations

Countries of recruitment

Italy

Study participating centre
Servizio Emodialisi Policlinico Borgo Roma
Piazzale LA Scuro 10
Verona
Italy
37134

Sponsor information

Organisation
Azienda Ospedaliera Universitaria Integrata Verona

Sponsor details
UOC Nefrologia e Dialisi dU (Nephrology and Dialysis Unit)
Piazzale Stefani 1
Verona
Italy
37126

Sponsor type
Other

Website
http://www.ospedaleuniverona.it/ecm/home

ROR
https://ror.org/00sm8k518

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Azienda Ospedaliera Universitaria Integrata Verona

Results and Publications

Publication and dissemination plan
Plan to publish the results of the study in a Nephrology Journal

Intention to publish date
30/11/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018	30/01/2019	Yes	No