

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

Submission date 30/08/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/10/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/01/2020	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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

Study type(s)

Treatment

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- α , 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(s)

Reduction Ratios (RR) of hepcidin and the inflammatory biomarkers (IL-6, TNF- α , Pentraxin 3 and C-reactive protein) are calculated using the formula $RR = (C_{pre} - C_{post}/C_{pre}) \times 100$ (where C_{pre} is the concentration just before dialysis and C_{post} the concentration at the end of dialysis).

Key secondary outcome(s)

Blood-side clearance of hepcidin and the inflammatory biomarkers (IL-6, TNF- α , 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 $K = Q_b \times (C_{bi} - C_{bo} / C_{bi})$, where Q_b is the blood flow rate, C_{bi} is the solute serum levels at the dialyzer inlet, and C_{bo} the solute serum levels at the dialyzer outlet.

Completion date

10/01/2015

Eligibility

Key inclusion criteria

1. Aged over 18 years.
2. Chronic hemodialysis patients on erythropoiesis-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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

ROR

<https://ror.org/00sm8k518>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Azienda Ospedaliera Universitaria Integrata Verona

Results and Publications

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