

Kinetics of solute removal with on-line hemodiafiltration: influence of duration and frequency of treatment

Submission date

02/12/2005

Recruitment status

No longer recruiting

Registration date

02/02/2006

Overall study status

Completed

Last Edited

23/10/2009

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☐ Results

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

GAMBRO 99/03

Study information

Scientific Title**Acronym**

Hemodiafiltration (HDF) optimisation

Study objectives

The aim of the study is to show if highly efficient and more frequent dialysis treatment is able to improve removal of low and high molecular weight uremic toxins. Clinical data on elimination and rebound kinetics of uremic toxins in a broad range of molecular weight should serve as the basis for the adjustment of kinetic models of solute removal during hemodiafiltration treatments. These models should allow for an optimisation of hemodiafiltration treatment parameters.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved on 18 October 1999 by the Freiburg Ethics Commission International (FECI)

Primary study design

Interventional

Study design

Four-period crossover

Study type(s)

Treatment

Health condition(s) or problem(s) studied

End stage renal disease

Interventions

Modification of treatment mode, frequency, drawing and analysis of blood samples

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Blood concentrations of small and large molecular weight uremic solutes

Key secondary outcome(s)

Modelling of solute kinetics

Completion date

30/06/2000

Eligibility**Key inclusion criteria**

1. Stable patients with renal end stage disease being on hemodialysis for at least six months
2. Residual urine volume less than 200 ml per day
3. Ages between 18 and 75 years

4. Body dry weight between 60 and 80 kg
5. Written consent
6. Well functioning vascular access

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Known human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV) infection
2. Miscellaneous acute or chronic infections
3. Known coagulation disturbances
4. Known incomppliance with respect to fluid restriction

Date of first enrolment

01/01/2000

Date of final enrolment

30/06/2000

Locations**Countries of recruitment**

Germany

Study participating centre

Holger-Crafoord-Str. 26

Hechingen

Germany

72379

Sponsor information

Organisation

Gambro Dialysatoren GmbH (Germany)

ROR

<https://ror.org/05jgtkc28>

Funder(s)**Funder type**

Industry

Funder Name

Grant by Gambro Corporate Research (Germany)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration