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

Submission date	Recruitment status	Prospectively registered
02/12/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
02/02/2006	Completed	Results
Last Edited	Condition category	Individual participant data
23/10/2009	Nutritional, Metabolic, Endocrine	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers GAMBRO 99/03

Study information

Scientific Title

Acronym

Hemodiafiltation (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 hemodiafiltraion 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 the Freiburg Ethics Commission International (FECI)

Study design

Four-period crossover

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Blood concentrations of small and large molecular weight uremic solutes

Secondary outcome measures

Modelling of solute kinetics

Overall study start date

01/01/2000

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 betweeen 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

10

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 incompliance 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)

Sponsor details

Holger-Crafoord-Str. 26 Hechingen Germany 72379

Sponsor type

Industry

ROR

https://ror.org/05jgtkc28

Funder(s)

Funder type

Industry

Funder Name

Grant by Gambro Corporate Research (Germany)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date
Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration