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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	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 02/02/2006	**Overall study status** Completed	
Last Edited 23/10/2009	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 summary
Not provided at time of registration