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Influence of different types of dialysis membranes on parameters of chronic inflammation

Submission date	Recruitment status	[_] Prospectively registered
17/03/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/03/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/03/2006	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
POL-FRA-1

Study information

Scientific Title

Acronym
INFLUX

Study objectives
The aim of the study is to evaluate the influence of dialysis membrane permeability on biological parameters that predict morbidity and mortality of hemodialysis patients with moderate chronic inflammation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Consulting committee for the protection of people in biomedical research, Bordeaux A (Comité Consultatif pour la Protection des Personnes dans la Recherche Biomédicale [CCPPRB] de Bordeaux A) - number 2004/49, June 18, 2004.

Primary study design
Interventional

Study design
Prospective, multicenter, randomised

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
End-stage renal disease

Interventions
Hemodialysis treatment with high-flux versus low-flux dialysers of the same type of chemical composition

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Plasma concentration of C-reactive protein

Key secondary outcome(s)
Advanced glycation end products, carboxymethyl lysine, asymmetric dimethyl arginine, fibrinogen, albumin and prealbumin, phosphate

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Medically stable end-stage renal disease patients on hemodialysis for 6 months or more
2. Age ≥18 years
3. C-reactive protein between 5 and 50 mg/l maximum one week before inclusion
4. Human immunodeficiency virus (HIV) and hepatitis C virus (HCV) serologies negative
5. Not under guardianship
6. AgHbs negative
7. Absence of vascular access thrombosis
8. Absence of clinically identifiable cause of chronic inflammation
9. Treatment in a dialysis unit providing water quality according to the European Pharmacopoeia
10. Statin medication allowed, but no introduction or modification during the study
11. Hemodialysis blood flow rates between 200 and 500 ml/min possible
12. Dialysis frequency 3-4 per week

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Age >75 years
2. Known pregnancy
3. Severe comorbidities with life expectancy <1 year
4. Cancer except skin cancer
5. Severe digestive pathologies
6. Chronic inflammatory diseases
7. Medication interfering with nutritional or inflammatory status
8. Treatment or intention to treat with immunosuppressive medication
9. Dialysis dose Kt/V <1.2, and dialysis time <10 hours per week
10. Treatment with hemofiltration or hemodiafiltration
11. Participation in another study during the preceding 30 days
12. Physically or mentally disabled patients

Date of first enrolment
10/02/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
France

Study participating centre
Hôpital Pellegrin
Bordeaux
France
33076

Sponsor information

Organisation
Gambro SAS (France)

ROR
https://ror.org/01mgtdr23

Funder(s)

Funder type
Industry

Funder Name
Gambro SAS

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration