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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