

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

Submission date
17/03/2006

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
24/03/2006

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
24/03/2006

Condition category
Urological and Genital Diseases

☐ 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

Prof Christian Combe

Contact details

Hôpital Pellegrin
Service de Néphrologie
Place Amélie Raba-Léon
Bordeaux
France
33076
christian.combe@chu-bordeaux.fr

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

Study design

Prospective, multicenter, randomised

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

Plasma concentration of C-reactive protein

Secondary outcome measures

Advanced glycation end products, carboxymethyl lysine, asymmetric dimethyl arginine, fibrinogen, albumin and prealbumin, phosphate

Overall study start date

10/02/2005

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

180

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)

Sponsor details

1-3, Boulevard Charles-de-Gaulle

Colombes

France

92707

georges.martin@gambro.com

Sponsor type

Industry

ROR

<https://ror.org/01mgtdr23>

Funder(s)

Funder type

Industry

Funder Name

Gambro SAS

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