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Role of diastolic dysfunction in the pathogenesis of dialytic associated hypotension and effect of systematic colloid infusion in refractory cases

Submission date
31/03/2011

Recruitment status
No longer recruiting

Registration date
18/05/2011

Overall study status
Completed

Last Edited
07/12/2012

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
AFSSAPS n° 021059

Study information

Scientific Title
Determining of the role of left ventricular diastolic dysfunction and diastolic heart failure in the pathogenesis of dialytic associated hypotension and studying the benefit of routine colloid infusion in hypotension prone dialysis patients (with diastolic dysfunction), who are unresponsive to preventive measures

Study objectives
The increasing number of elderly and diabetic patients and patients with cardiovascular disease may play a pivotal role in the pathogenesis of dialysis associated hypotension through left ventricular diastolic dysfunction and diastolic heart failure. The aim of this pilot study was to assess the potential benefit of systematic infusion of colloids during dialysis in hypotension prone patients who have diastolic dysfunction and are unresponsive to the usual preventive measures

Ethics approval required
Old ethics approval format

Ethics approval(s)
This trial received approval n°02-017 from the ethics committee of Henri Mondor University Hospital and was registered at the French Agency for Drugs and Health Devices AFSSAPS (n° 021059). 12/06/2002

Study design
Prospective cross-sectional cohort and prospective crossover study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
End stage renal failure/hemodialysis patients/hemodynamic instability during dialysis sessions

Interventions

1. Cross-sectionnal study of hemodialysis patients: Echocardiography performed 2 hours after a dialysis session and BNP measured at the beginning of mid week dialysis session
2. Cross-over single blind study (lasting 20 weeks) of systematic infusion of 200 ml of albumine 20% and gelatine 4% during 5 weeks each separated by a washout period (lasting 5 weeks)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Cross-sectionnal study of hemodialysis patients: E/A ratio, Color M-mode diastolic flow propagation velocity (Vp)
2. Cross-over study of systematic infusion of colloids: arterial pressure regulation, i.e. Systolic Blood Pressure (SBP) and Diastolic Blood Pressure, and the number of hypotensive episodes (defined as SBP < 100 mmHg, regardless of symptoms)

Secondary outcome measures
1. Cross-sectional study of hemodialysis patients :B-type natriuretic peptide (BNP), Cardiac index, Left-ventricular ejection fraction, Myocardial fractional shortening, Left ventricular mass index
2. Cross-over study of systematic infusion of colloids: nutritional status, ultrafiltration rate, dialysis quality microinflammatory status, oxidative stress, serum nitrate and nitrite levels

Overall study start date
01/01/2003

Completion date
30/06/2008

Eligibility

Key inclusion criteria
1. Hemodialysis patients
2. Age > 16 years and < 90 years
3. Dialysis vintage <10 years
4. Treated by intermittent bipuncture bicarbonate hemodialysis 3 times per week
5. Dialysis hypotension-prone patients identified in the prospective cross-sectionnal study who were unresponsive to preventive measures

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Prospective cross-sectional study : 100 patients, prospective crossover study of colloids : 16 patients

Key exclusion criteria
1. Left-ventricular ejection fraction < 40%
2. Malnutrition, anemia unresponsive to erythropoesis stimulating agents requiring transfusions, cancer or severe infection, inadequate dry weight assessed by echocardiography and echography of the vena cava inferior

Date of first enrolment
01/01/2003

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
France

Study participating centre
Service de Néphrologie et de Dialyse
Quincy sous Senart
France
91480

Sponsor information

Organisation
Association Quincy Recherche Clinique et Therapeutique (QRCT) (France)

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Sponsor type
Charity

Funder(s)

Funder type
Charity

Funder Name
Physicians Association of Claude Galien Hospital (Association Quincy Recherche Clinique et Thérapeutique - QRCT) (France)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2009		Yes	No
Results article	results	01/03/2011		Yes	No
Results article	results	20/10/2011		Yes	No