

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

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Guy Rostoker

Contact details

Service de Néphrologie et de Dialyse

Hopital Privé Claude Galien

2 Rue de Boussy

Quincy sous Senart

France

91480

+33 (0)1 69 39 92 01

rostotom@orange.fr

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 erythropoiesis 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)

Sponsor details

2 Rue du Moulin de Jarcy

Quincy sous Senart

France

91480

+33 (0)1 69 39 91 64

qrct@gsante.fr

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 |