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Effect of carvedilol on norepinephrine levels in hemodialysis patients

Submission date
27/08/2020

Recruitment status
No longer recruiting

Registration date
02/09/2020

Overall study status
Completed

Last Edited
01/09/2020

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dialysis is a procedure to remove waste products and excess fluid from the blood when the kidneys stop working properly. It often involves diverting blood to a machine to be cleaned. Normally, the kidneys filter the blood, removing harmful waste products and excess fluid and turning these into urine to be passed out of the body.
Studies have shown that dialysis patients can develop heart problems due to changes in nervous system activity.
The objective of the present study was to determine whether treatment with carvedilol can improve the symptoms of heart problems in patients on dialysis.

Who can participate?
Patients aged 18 years or above, with chronic kidney disease (CKD), having been on regular hemodialysis for more than 6 months.

What does the study involve?
Each patient was evaluated over a 14-day period. Hemodialysis was performed by medical staff who were unaware of the aim of the study. Patients and staff were both blinded to the additional treatment being administered: placebo on days 0 through 7; and carvedilol on days 8 through 14.

What are the possible benefits and risks of participating?
The benefit is better control of hypertension. The main risk is hypotension regarding the use of carvedilol.

Where is the study run from?
Mario Covas Hospital (Brazil)

When is the study starting and how long is it expected to run for?
October 2004 to August 2005

Who is funding the study?
The Brazilian National Council for Scientific and Technological Development (Brazil)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
151 Effect

Study information

Scientific Title
Effect of carvedilol on norepinephrine levels in hemodialysis patients: a prospective double-blind placebo-controlled clinical trial

Acronym
EFFECT

Study objectives
The objective of this unprecedented study was to determine whether the use of carvedilol correlates with norepinephrine levels in hemodialysis patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/10/2004, ABC Medical School Research Ethics Committee (Lauro Gomes ave, 2000, Santo Andre, Sao Paulo, Brazil, 09060870; +55 1149935400; no email provided), ref 087/2004

Study design
Prospective interventional non-randomized placebo-controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

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
Cardiovascular disease in hemodialysis patients

Interventions
This was a prospective study involving a cohort of stable patients recruited from eligible patients who were undergoing hemodialysis at the study centre hemodialysis clinic three times a week during the period of study

Each patient was evaluated over a 14-day period. Hemodialysis was performed by medical staff who were unaware of the aim of the study. Patients and staff were both blinded to the additional treatment being administered: placebo on days 0 through 7; and carvedilol on days 8 through 14. The carvedilol was given in increasing doses, from a minimum of 3.123 mg (twice a day) on day 8 to a maximum of 9.375 mg (twice a day) on day 14. Noninvasive (Holter) monitoring was performed on day 0 and on day 14. Plasma levels of norepinephrine were determined before and after hemodialysis on day 0 and day 14. Before and after hemodialysis on days 0, 7, and 14, patients completed a symptom questionnaire.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Carvedilol

Primary outcome measure

Mean plasma norepinephrine level measured by High Performance Liquid Chromatography (HPLC) at 0 and 14 days

Secondary outcome measures
Number of ventricular arrhythmias registered by Holter monitoring at 0 and 14 days

Overall study start date
01/10/2004

Completion date
01/08/2005

Eligibility

Key inclusion criteria
1. 18 years or older
2. Having chronic kidney disease (CKD)
3. Having been on regular hemodialysis for more than 6 months
4. Having a hemoglobin level >10 mg/dl
5. Having a Kt/V >1.2 in more than three consecutive measures
6. Patients gave written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
26

Total final enrolment
26

Key exclusion criteria
1. Active liver disease
2. Any other decompensated disease
3. Previously used beta-blockers
4. Active infection
5. Hospitalized

Date of first enrolment
01/12/2004

Date of final enrolment
01/07/2005

Locations

Countries of recruitment
Brazil

Study participating centre
Mario Covas Hospital
Henrique Calderazzo street 321
Santo Andre
Sao Paulo
Brazil
09190615

Sponsor information

Organisation
University of Sao Paulo

Sponsor details
Teodoro Sampaio Street 115
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Sponsor type
University/education

Website
http://www5.usp.br/en/

ROR
https://ror.org/036rp1748

Funder(s)

Funder type
Government

Funder Name
Conselho Nacional de Desenvolvimento Científico e Tecnológico

Alternative Name(s)
Brazilian National Council for Research and Development, National Council for Scientific and Technological Development, CNPq

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Brazil

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal.

2008 results published in thesis https://teses.usp.br/teses/disponiveis/5/5159/tde-05082008-135611/publico/joaoisuksuh.pdf

Intention to publish date
01/09/2020

Individual participant data (IPD) sharing plan
All data, comments, informed consent model, and statistical analysis are available to the public permanently at the weblink above in the form of a monograph, or are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request