

Effect of carvedilol on norepinephrine levels in hemodialysis patients

Submission date 27/08/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/09/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/09/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Dr Joao Isuk Suh
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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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 - Conselho Nacional de Desenvolvimento Científico e Tecnológico, National Council for Scientific and Technological Development (Conselho Nacional de Desenvolvimento Científico e Tecnológico), CNPq

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Brazil

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes