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Aerobic versus anaerobic exercise and oral nutritional supplementation in nutritional status and physical function of adults hemodialysis patients

Submission date
11/11/2016

Recruitment status
No longer recruiting

Registration date
06/12/2016

Overall study status
Completed

Last Edited
15/10/2019

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Hemodialysis is a process of purifying the blood of a person whose kidneys are not working normally. A condition called protein-energy wasting, where the body has decreased stores of protein and fat, is common in patients undergoing hemodialysis. Studies have looked at the benefits of oral nutritional supplements, resistance exercise (e.g., weight training) and aerobic exercise (e.g., cycling) on nutrition and physical function, but it is not known what kind of treatment is best for patients. The aim of this study is to compare the effect of oral nutritional supplementation plus resistance exercise, oral nutritional supplementation plus aerobic exercise, and oral nutritional supplementation alone.

Who can participate?
Patients aged 18 to 45 undergoing hemodialysis

What does the study involve?
Participants are randomly allocated to receive one of three treatments two times per week for 12 weeks: either oral nutritional supplement plus resistance exercise, oral nutritional supplement plus aerobic exercise, or oral nutritional supplement alone. At the end of the study participants' body measurements, blood test results, physical function and quality of life are assessed.

What are the possible benefits and risks of participating?
It has been shown that exercise and oral nutritional supplements are safe and beneficial. Low blood pressure and symptoms such as diarrhoea and nausea have been associated with oral nutritional supplements, but there is a lack of evidence supporting this.

Where is the study run from?
Hospital General de México, Dr Eduardo Liceaga (Mexico)

When is the study starting and how long is it expected to run for?
January 2016 to September 2017

Who is funding the study?
Hospital General de México, Dr Eduardo Liceaga (Mexico)

Who is the main contact?
1. Dr Lucía Monserrat Pérez
2. Miss Geovana Martin

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DI/16/105-B-04-128

Study information

Scientific Title
A prospective randomized trial, Aerobic Versus ANaerobic exercise and oral nuTritional supplEmentation in nutritional status and physical function of adults HEMOdialysis Patients: the AVANTE-HEMO study

Acronym
AVANTE-HEMO

Study objectives
Hemodialysis (HD) patients who perform resistance exercise (RE) + receive oral nutritional supplementation (ONS) will have better parameters of nutritional status and physical function than patients of the aerobic plus oral nutritional supplementation group and oral nutritional supplementation group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hospital General de México, Dr. Eduardo Liceaga ethics committee, 28/09/2016, ref: DI/16/105-B-04-128

Study design
Parallel single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied

Hemodialysis

Interventions

Method of randomization: A blocked design will be used, using an online statistical computing web programming (www.randomizer.org) to generate the randomization schedule, 14 sets of 3 unique numbers per set range from 1 to 3 (representing the three treatment arms).

Control arm
During the HD sessions, patients receive a can of a specialized oral nutritional supplement for maintenance dialysis patients that consists of 480 kcal, 20 g protein and 20 g lipids (Enterex RNL, Pisa Laboratories). Enterex RNL contains omega-3 and omega-6 fatty acids, maltodextrin and sucralose.

Aerobic exercise arm
Patients of this group receive the same specialized oral nutritional supplement during the HD session, half of the a can is administered during the first hour of the HD session and the other half after the AE routine. Aerobic exercise consists of pedaling a stationary bike for the first two hours of the HD session, the optimal exercise time is established during the first session, then is gradually increased to reach 20-30 minutes. The scale of perceived exertion Borg (6-20) is used to establish the intensity of the exercise (moderate intensity, 12-13).

Resistance exercise arm
Patients of this group receive the same specialized oral nutritional supplement during the HD session, half of the a can is administered during the first hour of the HD session and the other half after the RE routine. Patients are trained for three months according to an adaptation to the program “Exercise: A Guide for People on Dialysis”. Four types of resistance exercise are performed during the second hour of the HD session (four sets of 20 repetitions for 40 min). TheraBand Latex Resistance Bands are used to individualize the exercise. The scale of perceived exertion Borg (6-20) is used to establish the intensity of the exercise (moderate intensity, 12-13)

Frequency and duration of treatment: Two times per week for 12 weeks (40 minutes of resistance exercise and 30 minutes of aerobic exercise)
Follow-up: 12 weeks

Intervention Type

Mixed

Primary outcome measure

Measured at baseline and 3 months:
1. Weight: The weight reached by the patient at the end of a session which has removed the maximum fluid without inducing hypotension (seca 676 wheelchair scale, wireless)
2. Body mass index: body mass divided by the square of the body height
3. Anthropometric measurements: skinfold thickness (biceps, triceps, subescapular, supra-iliac) using a Lange skin fold caliper to estimate:
3.1. Fat mass percentage: calculated using Siri's (1956) equation = (4.95/density)-4.50*100
3.2. Mid-upper arm circumference: measured at the mid-point between the tip of the shoulder and the tip of the elbow (olecranon process and the acromium)
3.3. Mid arm muscle circumference = mid arm circumference – (π x triceps skinfold thickness)
3.4. Bone-free arms muscle area: males = [(midarm circumference (cm) - π x triceps (cm)]2/4 π) - 10; females = [(midarm circumference (cm) - π x triceps (cm)]2/4 π) - 6.5
4. Handgrip strength, measured using hand dynamometry (Smedley III, Takei Scientific

Instruments, Niigata City, Japan)
5. Serum albumin, measured using the bromocresol purple albumin assay
6. Physical function, measured using the six-minute walk test according to the American Thoracic Society Guidelines, Time Up and Go Test (Podsiadlo, D et al. J Am Geriatr Soc, 1191;39:142-148), five times sit to stand test
7. Bioelectrical impedance analysis (resistance, reactance and phase angle), measured using conventional impedance (single frequency; Quantum System, RJL Systems, Clinton Township, MI, USA)

Secondary outcome measures
Measured at baseline and 3 months:
1. Quality of life, measured using the Kidney Disease Quality of Life Short Form (KDQOF-SF)
2. C Reactive Protein, measured using the nephelometric assay

Overall study start date
01/01/2016

Completion date
01/09/2017

Eligibility

Key inclusion criteria
1. Regular HD two or more times a week
2. Signed informed consent
3. Any gender
4. Age >18 to <45 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
45

Key exclusion criteria
1. Patients with an amputation
2. Hospitalization in the last 3 months
3. Unsatisfactory attendance at HD sessions

4. Pregnancy
5. Excessive pallor
6. Severe dyspnea
7. Femoral fistula
8. Arrhythmias
9. Precordial pain
10. Orthopedic or neurological compromises or cognitive alterations affecting their participation in the study

Date of first enrolment
01/11/2016

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
Mexico

Study participating centre
Hospital General de México, Dr Eduardo Liceaga
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website

http://www.hgm.salud.gob.mx/

ROR
https://ror.org/01php1d31

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital General de México, Dr Eduardo Liceaga

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact journal, such as Journal of Renal Nutrition or Nutrients in 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Geovana Martin Alemañy. The trialists can share data (variables) represented in the subsequent results publication and if someone needs information for a systematic review with meta-analysis, the data will be available before the publication of the original article. The trialists are going to share anonymous information and the datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		16/10/2018	12/12/2018	No	No
Results article	results	01/03/2020	15/10/2019	Yes	No