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Effectiveness and safety of the intradialytic oral nutrition over nutritional markers and intradialytic hypotension in comparison with home complementation in patients undergoing hemodialysis

Submission date 11/07/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/07/2017	**Overall study status** Completed	
Last Edited 09/08/2022	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Hemodialysis (HD) is a process of purifying the blood of a person whose kidneys are not working normally. HD causes an inflammatory effect which decreases the appetite, increases certain gastrointestinal (digestive system) symptoms and consequently the patients consume fewer nutrients, increasing the risk of developing protein energy wasting (reduced body protein and fat mass). This could be treated and even prevented with oral nutritional supplementation containing extra protein and calories. It's been suggested that oral supplementation during HD treatment, called intradialytic oral nutrition supplementation (ION), can improve survival. Despite the proposed benefits, health personnel see ION as a risk factor for many adverse events such as intradialytic hypotension (low blood pressure) and other gastrointestinal and adverse events like nausea, vomiting, diarrhea and infections. The prevalence of these events has been little studied, and health personnel in HD units should not base their decision not to give ION based on this limited evidence. Therefore, the aim of this study is to determine the safety of ION over intradialytic hypotension and its effectiveness over some clinical nutritional markers in comparison with standard supplementation (at home).

Who can participate?
Patients aged 18 to 65 who are receiving chronic (long-term) HD treatment

What does the study involve?
Participants are randomly allocated to one of two group. Both groups consume a liquid supplement containing extra protein and calories. The intervention group consume the supplement at minutes 60-75 and 210-225 of a HD session. The control group consume two portions of the supplement at home on a specific schedule on a non-HD day. The incidence of intradialytic hypotension is assessed during HD sessions.

What are the possible benefits and risks of participating?
This study may increase the limited general knowledge of the safety and effectiveness of ION, and may increase health personnel's confidence for giving supplements during HD treatment and therefore prevent or treat protein energy wasting in HD patients. Possible benefits for participants include improvement in protein levels, sensation of general wellness, and improvements in appetite and calorie-protein intake. Risks for patients include nausea, vomiting, diarrhoea, aspiration and hypotension during HD treatment.

Where is the study run from?
National Institute of Medical Science and Nutrition Salvador Zubirán (Mexico)

When is the study starting and how long is it expected to run for?
September 2017 to February 2018

Who is funding the study?
National Institute of Medical Science and Nutrition Salvador Zubirán (Mexico)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2231

Study information

Scientific Title
Effectiveness and safety of the intradialytic oral nutrition over nutritional markers and intradialytic hypotension in comparison with home complementation in patients undergoing hemodialysis: a noninferiority equivalence randomized trial

Study objectives
Patients undergoing hemodialysis (HD) are in risk for developing Protein Energy Wasting (PEW) which increases risk for morbidity and mortality. PEW has many components in which energy consumption is crucial. Intradialytic supplementation is an effective anabolic strategy for improving albumin, prealbulmin and protein homeostasis. Despite these effective outcomes, health personnel perceive intradialytic supplementation as a risk for intradialytic hypotension and other gastrointestinal complications.

Study hypotheses:
1. Muscular strength, energy consumption and phase angle will increase at least 10% of their basal value after 3 months of intervention with a specific renal supplement.
2. There won't be more than 10% on the increase of the presence of intradialytic hypotension after intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics and investigation committee from Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubirán, 12/06/2017, ref: 2231

Study design
Randomized controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hemodialysis

Interventions
Simple random allocation according to shift-day treatment for hemodialysis (HD) session. Both groups will consume a liquid renal specific supplement which grants 19 grams of protein and 434 Kcal per 237 ml:
1. The intervention group will consume 120 ml at minutes 60-75 and 210-225 of a hemodialysis session.
2. The control group will consume two portions of 120 ml at home on a specific schedule on a non-HD day.

Intervention Type
Supplement

Primary outcome(s)

Incidence of intradialytic hypotension, obtained from the nurse sheet at 60, 90, 120, 150, 180, 210, 240 minutes of HD sessions

Key secondary outcome(s))
1. Sleep quality, analysed using Pittsburgh scale applied by a trained professional at the beginning and at the end of the intervention
2. Muscle strength, analysed using a dynamometer, requesting patients to press it as hard as they can after HD treatment. The measurement will be registered for 3 times on each arm
3. Calorie-protein intake, measured with a 3-day dietary register. Each patient will register their food consumption during 3 days: 1) HD day, 2) No HD session weekday and 3) Weekend day. Data will be analyzed by dietary software
4. Phase angle, determined with multifrequency BIA device after HD session
5. Incidence of nausea, vomiting, cramps, obtained from the nurse sheet (present/absent) at 60, 90, 120, 150, 180, 210, 240 minutes of HD sessions

Completion date
01/03/2019

Eligibility

Key inclusion criteria
1. Chronic hemodialysis (> 3 months)
2. Program of 3 sessions per week
3. Adults aged 18-65
4. Kt/V > 1.2 or URR > 65%
5. Agree to participate and informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Amputee of any extremity
2. Renal transplant within 3 next months
3. HD as treatment for kidney injury
4. Hospitalization at least one month prior to the initiation of the study

Date of first enrolment
28/11/2017

Date of final enrolment
30/12/2018

Locations

Countries of recruitment
Mexico

Study participating centre
National Institute of Medical Science and Nutrition Salvador Zubirán
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Sponsor information

Organisation
National Institute of Medical Science and Nutrition Salvador Zubirán

ROR
https://ror.org/00xgvev73

Funder(s)

Funder type
Research organisation

Funder Name
National Institute of Medical Science and Nutrition Salvador Zubirán

Funder Name
Abbott Laboratories (Mexico)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. María de los Ángeles Espinosa Cuevas (angespinosac@gmail.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/07/2022	09/08/2022	Yes	No
Basic results		20/03/2020	20/03/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes