

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

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<b>Registration date</b> 13/07/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/08/2022	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## 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 groups. Both groups consume a liquid supplement containing extra protein and calories. The intervention group consumes the supplement at minutes 60-75 and 210-225 of a HD session. The control group consumes 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?

Dr María de los Ángeles Espinosa Cuevas  
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## Contact information

### Type(s)

Scientific

### Contact name

Dr María de los Ángeles Espinosa Cuevas

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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, prealbumin 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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

## **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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

01/09/2017

## **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

### **Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

70

**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**

Vasco de Quiroga 15

Tlalpan

14080 Ciudad de México

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## **Sponsor information**

**Organisation**

National Institute of Medical Science and Nutrition Salvador Zubirán

**Sponsor details**

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**Sponsor type**

Research organisation

**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****Publication and dissemination plan**

The trialists don't have an exact date for publishing the results but they want it to be within 6 months of the overall trial end date. Also, they want it to be presented on the next international congress of the international society of renal nutrition and metabolism (Genova, Italy) as an oral or poster presentation and published in a high-impact peer reviewed journal.

**Intention to publish date**

01/08/2018

**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?
<a href="#">Basic results</a>		20/03/2020	20/03/2020	No	No
<a href="#">Results article</a>		22/07/2022	09/08/2022	Yes	No