

# Nutritional outcomes for a randomised investigation of nutritional supplements in patients who receive haemodialysis

<b>Submission date</b> 12/03/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/04/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/03/2015	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Haemodialysis is a form of renal replacement therapy that clears the blood of toxins when a person's own kidneys are unable to do so. The haemodialysis process unfortunately also filters out the building blocks of protein and uses energy. Patients with kidney disease often have a poor appetite and limited dietary intake because of their kidney problems and this in combination with the effects of haemodialysis can lead to the development of malnutrition. Studies have shown between 20% and 50% of haemodialysis patients to be malnourished and malnutrition can worsen clinical outcomes and increase the risk of hospitalisation. This is an initial study to assess the use of an intradialytic (meaning whilst on haemodialysis) nutritional supplement on nutritional status and whether this works better than normal care.

### Who can participate?

Participants must be over the age of 18, receive regular haemodialysis and have a measure of height for weight that is lower than advised for a person receiving haemodialysis.

### What does the study involve?

Participants are randomly allocated to one of two groups: an intervention and a control group. The intervention group will take a nutritional supplement each dialysis session from a choice of drinks or puddings in various flavours. The control group will receive standard care. Each group will complete a short questionnaire about their wellbeing each time they attend haemodialysis. They will have their hand grip strength measured and fill in a Quality Of Life questionnaire, at the start and at 1 and 2 months. Their weight will also be recorded along with routine blood tests.

### What are the possible benefits and risks of participating?

There may not be any benefit to the participants directly, in part due to the study being of very short duration but the results of the study may help to improve the nutritional wellbeing of people receiving haemodialysis in the future.

The risks to people who participate are very small as nutritional supplements are routinely used with people who have kidney problems.

Where is the study run from?

The trial will be conducted on one haemodialysis unit in a Yorkshire hospital (UK).

When is the study starting and how long is it expected to run for?

The study will run between May and September 2013.

Who is funding the study?

The University of Sheffield (UK)

Who is the main contact?

Louise Jackson, Senior Renal Dietitian

[louise.jackson@sth.nhs.uk](mailto:louise.jackson@sth.nhs.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Louise Jackson

### Contact details

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S5 7AU

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

001

## Study information

### Scientific Title

Nutritional OUTcomes from a Randomised Investigation of intradialytic oral nutritional Supplements in patients receiving Haemodialysis

### Acronym

NOURISH

## **Study objectives**

The rationale for this trial is to assess the efficacy of oral nutritional supplements on nutritional status if provided whilst participants receive haemodialysis. Nutritional status will be measured using a variety of indicators. However, this is a feasibility trial that primarily aims to assess recruitment and retention of participants, delivery and acceptability of the intervention, data collection and completion rates along with analysis of results.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

NRES Committee Yorkshire & The Humber - Leeds East. REC reference: 13/YH/0092. IRAS project ID: 121918. Approval dated 15/04/13.

## **Study design**

Single centre two-arm parallel group randomised controlled pilot trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Quality of life

## **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**

Haemodialysis - a form of renal replacement therapy

## **Interventions**

Oral nutritional supplements versus standard care in haemodialysis patients

An oral nutritional supplement will be provided to the intervention group each dialysis session for 2 months.

A quality of life assessment, dietary interview and handgrip strength will be collected at baseline, 1 month and completion of the study (month 2) on both the intervention and control groups.

The control group will continue to receive standard care but not the oral nutritional supplement.

## **Intervention Type**

Supplement

## **Phase**

Not Applicable

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

Nutritional supplements

**Primary outcome measure**

1. Recruitment rate, refusal, withdrawal and dropout rate
2. Barriers to recruitment
3. The ability to provide the intervention as per protocol
4. Palatability and preference for types of oral nutritional supplements
5. The feasibility, acceptability and appropriateness of data collection methods
6. Data completion rates

**Secondary outcome measures**

The secondary outcomes relate to the efficacy of intradialytic nutritional supplementation on nutritional status. These parameters will help determine the most appropriate outcome measures and timing of data collection points for a larger RCT. Measures are:

1. Handgrip dynamometry
2. Quality of Life
3. Weight
4. Dietary intake

**Overall study start date**

01/05/2013

**Completion date**

30/09/2013

**Eligibility****Key inclusion criteria**

1. Adult male or female haemodialysis patients
2. Received maintenance haemodialysis for at least 6 months
3. Receives haemodialysis at least 3 times per week
4. Has a body mass index of 22kg/m<sup>2</sup> or less

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

30

**Key exclusion criteria**

1. Amputees
2. Those with significant oedema
3. Patients who are unable to communicate fluently in English

4. Those receiving nutritional supplementation prior to the study commencing or within 1 month of starting the study
5. Those with persistent hyperkalaemia or hyperphosphataemia

**Date of first enrolment**

01/05/2013

**Date of final enrolment**

30/09/2013

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre****Dietetic Department**

Sheffield

United Kingdom

S5 7AU

## **Sponsor information**

**Organisation**

Sheffield Teaching Hospitals NHS Foundation Trust (UK)

**Sponsor details**

c/o Anna Leesley

Research and Development Department

11 Broomfield Road

Sheffield

England

United Kingdom

S10 2SE

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/018hjpz25>

# Funder(s)

## Funder type

University/education

## Funder Name

University of Sheffield (UK) - Student Thesis as part of a Masters in Clinical Research

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	07/10/2013		Yes	No
<a href="#">Results article</a>	results	01/12/2015		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No