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

Submission date
12/03/2013

Recruitment status
No longer recruiting

Registration date
09/04/2013

Overall study status
Completed

Last Edited
30/03/2015

Condition category
Urological and Genital Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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 persons 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
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Contact information

Type(s)
Scientific

Contact name
Mrs Louise Jackson

Contact details
Dietetic Department
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Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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(s)
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

Key secondary outcome(s))

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

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/m2 or less

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Dietetic Department
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

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

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?
Results article	results	01/12/2015		Yes	No
Protocol article	protocol	07/10/2013		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes