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Can increased dietary fibre reduce laxative requirement in PD patients?

Submission date
18/06/2010

Recruitment status
No longer recruiting

Registration date
18/06/2010

Overall study status
Completed

Last Edited
30/08/2016

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients with kidney disease need dialysis to replace the work their kidneys are not able to do. One of the types of dialysis available is called Peritoneal Dialysis (PD). It relies on a special fluid being drained in and out of the patients body. If a PD patient becomes constipated, this fluid cannot drain out properly. As a result, the dialysis process stops working. All PD patients are given laxatives to prevent them from becoming constipated. Rather than rely on laxative medicine, this study aimed to improve the intake of dietary fibre as a means of preventing constipation.

Who can participate?
All adult patients on PD were invited to take part if they were using laxatives regularly and wanted to try an alternative.

What does the study involve?
Patients were randomly put into one of three groups. The first group was given dietary fibre in the form of a white powder that dissolved easily in drinks and soft food. The second group was given a white powder that looked the same but had no fibre. This is called a placebo. These two groups did not know which of the powders they had been given. They were told to mix the powder with any drink or food each day for 4 weeks. They had to start gradually in case the powder caused them any discomfort. They were told to continue taking their usual laxatives until they could tell that the powder was having an effect. They were shown how to measure the effect the powder might be having by looking at their stools. If their stools became looser, they were told to reduce their laxatives but keep going with the powder. The third group were given a special diet chart that listed foods containing dietary fibre that were safe for kidney patients to eat. They were told to try and include six to nine items from the list every day to see if they could improve their intake of dietary fibre using normal food.

What are the possible benefits and risks of participating?
The advantage of taking part would be to use a more natural way of controlling bowel function rather than relying on medication. There were no risks involved with this trial. None of the interventions required patients to make changes to their existing therapeutic dietary advice or their medication.

Where is the study run from?
The study was designed by one of the Renal Dietitians and originally tried out in Portsmouth. It was then extended to include other renal units across England. These were Kings College London, York, Royal Berkshire, Sheffield, Exeter, Truro, Plymouth, Kent and Canterbury. In all cases, the work was carried out by one of the Renal Dietitians on each Unit.

When is the study starting and how long is it expected to run for?
The study ran from March 2009 to August 2010.

Who is funding the study?
The study was funded by a grant from the British Renal Society.

Who is the main contact?
Debbie Sutton, Renal Research Dietitian
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Contact information

Type(s)
Scientific

Contact name
Mrs Debbie Sutton

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5807

Study information

Scientific Title
A multicentre randomised trial to assess whether increased dietary fibre intake (using a fibre supplement or high fibre foods) reduces laxative requirement in free living Peritoneal Dialysis patients

Study objectives
The main aim of this study is to investigate whether a daily bowel habit of appropriate consistency may be achieved through a higher fibre diet and minimal use of laxatives.

Objectives:
We will conduct the study to:
1. Establish current bowel habits, fibre intake, laxative use and costs, and the prevalence of constipation among all peritoneal dialysis (PD) programme patients
2. Test whether an increase in dietary fibre intake by 6 - 12 g per day (using a fibre supplement or high fibre food) results in improved bowel habits and reduced laxative use
3. Ensure that the treatment has no adverse effects on fluid balance or laboratory parameters (potassium, phosphate)
4. Investigate whether an increased fibre intake improves lipid profile

Ethics approval required
Old ethics approval format

Ethics approval(s)
Portsmouth IOW and SE Hants REC approved on the 18/12/2008 (ref: 08/H0501/123)

Study design
Multicentre randomised interventional treatment 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Renal and Urogenital; Subtopic: Renal and Urogenital (all Subtopics); Disease: Renal

Interventions
1. Fibre supplement arm
2. High dietary fibre arm
3. Placebo arm

The length of study period in each arm is 4 weeks.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Regular bowel activity, measured once at the end of the 4 week intervention period

Secondary outcome measures
1. Has stopped their laxatives
2. Stools equal to 3, 4 or 5 on the Bristol Stool Form

Measured once at the end of the 4 week intervention period.

Overall study start date
01/03/2009

Completion date
31/08/2010

Eligibility

Key inclusion criteria
1. PD patient for minimum 3 months
2. Regular user of laxatives
3. Aged greater than 18 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 100

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/03/2009

Date of final enrolment
31/08/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Portsmouth - Queen Alexandra Hospital
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Portsmouth Hospitals NHS Trust (UK)

Sponsor details
Southwick Hill Road
Cosham
Portsmouth
England
United Kingdom
PO6 3LY

Sponsor type
Hospital/treatment centre

Website
http://www.porthosp.nhs.uk/

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Research organisation

Funder Name

British Renal Society

Alternative Name(s)
BRS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

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