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Nutrition support in inactive Crohn's disease

Submission date
24/01/2014

Recruitment status
No longer recruiting

Registration date
31/01/2014

Overall study status
Completed

Last Edited
05/10/2020

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
People with Crohn's disease (a long-term condition causing inflammation of the lining of the digestive system) may experience a number of nutritional deficiencies even at times when their disease is not active. This study aims to look at the feasibility of carrying out a study to compare dietary counselling to standard written information to manage under-nutrition in people with Crohn's disease.

Who can participate?
Patients aged 18-65 with Crohn's disease in its inactive state attending outpatient appointments at Guy's and St Thomas' NHS Trust.

What the study involve?
Participants are randomly allocated to one of two groups. Both groups receive standard care in the form of written dietary information increasing portion size, meal frequency, food choice, nutrient density and food fortification. One group also receives dietary counselling tailored to provide an additional 600 kcal/d for a period of two months. At the end of the study, interviews are conducted to measure participant acceptability.

What are the possible benefits and risks of participating?
The participants may view the opportunity to receive well-established dietary counselling as a benefit of the study. The main disadvantages are the burden of participating in a study, the need to make dietary changes and the need to visit the research centre to carry out measurements on two occasions.

Where is the study run from?
Guy's and St Thomas' NHS Trust (UK)

When is the study starting and how long is it expected to run for?
February 2014 to May 2014

Who is funding the study?
King's College London (UK)

Who is the main contact?
Sheena Visram
sheena.visram@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Kevin Whelan

Contact details
Diabetes and Nutritional Sciences Division
King's College London
4th Floor Franklin-Wilkins Building
150 Stamford Street
London
United Kingdom
SE1 9NH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Detecting and managing undernutrition in adults with inactive Crohn's Disease: feasibility randomised comparative trial of oral nutritional support

Study objectives
The feasibility study will allow methodology, study design and outcome measures to be tested and a key outcome will be to measure patients' perceptions of the interventions, design and outcomes. This will provide essential information to inform the design of an adequately powered multicentre trial of oral nutritional support.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West Liverpool East, ref: 13/NW/0854 - approval pending

Study design
Feasibility randomised comparative trial: single centre two-armed parallel groups

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact sheena.visram@kcl.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Nutritional support for inactive Crohn's disease

Interventions
Participants will be randomised to two groups:
1. Intervention group: Receives standard care in the form of written information. In addition, they will receive dietary counselling individually tailored to increase dietary intake by 600 kcal /day over a period of two months.
2. Comparison group: Standard care only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Recruitment rate, retention, attrition and feasibility
2. Eligibility criteria including screening for under-nutrition, study design and methodology
3. Qualitative interviews on experience of participation

Measured by Interview Acceptability Interview at at baseline and two months

Secondary outcome measures
1. Nutritional outcome measures (measured by anthropometry and food record charts)
2. Clinical Outcomes (markers of disease activity and a Stool and Symptom Diary)
3. Patient centred outcome measures (measured by questionnaires)

All completed at baseline and after two months

Overall study start date

01/02/2014

Completion date
30/09/2014

Eligibility

Key inclusion criteria
1. Men and women aged ≥18 years
2. Diagnosis of Crohn's disease for duration of at least 6 months confirmed by standard clinical, histological and radiological criteria
3. Crohn's disease in remission as defined by Harvey Bradshaw score of < 5
4. Stable medications (see exclusion criteria), no recent surgery (see exclusion criteria) and stable symptoms for at least 2 months
5. BMI < 20 kg/m2
6. A willingness to participate
7. Individuals able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24 participants. Each group will aim to recruit 12 participants.

Total final enrolment
7

Key exclusion criteria
1. Patients with active Crohn's disease
2. Use of the following treatments: antibiotics, non-steroidal anti-inflammatory drugs (NSAIDs) during the preceding week
3. Currently taking steroids
4. Recent changes in dose to the following treatments: azathioprine, 6-mercaptopurine, methotrexate or α-TNF agents during the preceding 12 weeks, oral 5-aminosalicylate (5-ASA) or steroids during the preceding 4 weeks
5. Previous pan-proctocolectomy, pure perianal disease or short bowel syndrome
6. Stenotic disease
7. Sepsis or fever
8. Diabetes or coeliac disease (by serology and/or duodenal biopsy)
9. Other concomitant serious comorbidity e.g. significant hepatic, renal, endocrine, respiratory, neurological or cardiovascular disease

10. Pregnancy or lactation
11. Taking any medications with the potential to influence gastrointestinal symptoms unless taking a long-term stable dose that is unlikely to change or stop during the trial
12. Currently receiving oral nutritional supplements, enteral or parenteral nutrition, or having received dietary counselling or oral nutritional supplements, enteral or parenteral nutrition, in the previous 3 months prior to study commencement
13. Non fluent English

Date of first enrolment
01/02/2014

Date of final enrolment
01/05/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
United Kingdom
SE1 9NH

Sponsor information

Organisation
King's College London (UK)

Sponsor details
c/o Keith Brennan
Room 1.8 Hodgkin Building
Guys Campus
London
England
United Kingdom
SE1 4UL

Sponsor type
University/education

ROR

https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
King’s College London

Alternative Name(s)
Collegium Regale Londiniense, King's, KCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No