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Alginate formulations for enhancing colonic health

Submission date	Recruitment status	[X] Prospectively registered
13/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/01/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/04/2019	Digestive System	

Plain English summary of protocol

Background and study aims
Manucol LD is an alginate which comes from seaweed. Eating seaweeds is good for you. People in Asia who eat lots of it have less chance of developing certain disease such as bowel cancer and inflammatory bowel disease. Seaweeds are essentially a fibre and this product that is extracted from it (the alginate) is used throughout the food industry in products such as ice creams, sauces and jams, and in a number of medicines such as Gaviscon. The active ingredient in seaweed is not accurately known, however alginates are thought to play a key role in its beneficial effects. Through scientific research, it has been found that these alginates can bind iron and other heavy metals and are not broken down by digestive processes in the gut. It is also known that iron which is unabsorbed can have negative effects on the bowel such as inflammation and changes in the levels of good and bad bacteria in the gut. The researchers carrying out this study are interested in using a form of alginate which is altered for delivery to the human colon. This alginate can bind iron in the colon and so reduce the damaging effects of this highly reactive metal. Here, the effect of various doses of alginates in normal healthy people are studied with a view to taking this forward in patients with inflammatory bowel disease or those at risk of developing bowel cancer. This alginate is found in a range of foods and therefore safe for consumption. This study will test this foodstuff at a higher concentrations to see if it is acceptable and easy to consume on a daily basis.

Who can participate?
The study aims to recruit 16 healthy male or female volunteers over the age of 18 years through advertising at the University of Birmingham and the University Hospitals of Birmingham.

What does the study involve?
Participants are asked to attend 3 visits over a 1 month period. Participants are requested to take the Manucol LD on a daily basis, keep a record of when it is taken and if there are any changes in their bowel habit e.g. frequency. At each of these 3 visits they are asked to provide a stool sample (to assess the levels of good and bad bacteria), have blood tests (as markers of general health) and fill in a quality of life questionnaire.

What are the potential benefits and risks of participating?
There will be no direct benefit to individuals taking part in the study. As the Manucol LD is

essentially a foodstuff and found in a number of products on the market no problems are anticipated. However as it is a fibre it may cause some bloating and change to participants' bowel habit. The disadvantages of taking part are the inconvenience entailed in adhering to study protocol and visit schedule. Another drawback is the minor discomfort associated with the two blood tests at the beginning, middle and end of the study.

Where is the study run from?
University of Birmingham in collaboration with the Wellcome Trust Clinical Research Facility at the Queen Elizabeth Hospital in Birmingham (UK)

When is the study starting and how long is it expected to run for?
October 2014 to August 2015

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A physiological study to assess the acceptability of daily alginate (Manucol LD) consumption in healthy volunteers

Acronym
ALENCOL

Study objectives
Consuming a daily alginate (Manucol LD) is acceptable

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Edgbaston, 20/08/2015, ref: 15/WM/0221

Study design
Prospective single-centre non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

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
This physiological study aims to look at the acceptability of consuming a daily alginate which is thought to improve colonic health.

Interventions
Objectives
1. To evaluate the acceptability of supplementation of Manucol LD in healthy subjects for 28 days.
2. To explore the benefit of Manucol LD on bifidobacteria.

Participants take Manucol LD daily for 28 days. They keep a record of when it is taken and if there are any changes in bowel habit. They attend the study centre 3 times over this period where they provide stool and blood samples and complete a quality of life questionnaire..

Intervention Type
Supplement

Primary outcome measure
General acceptability of Manucol LD by the end of the study period

Secondary outcome measures

1. Effect of Manucol LD on quality of life measured over the 1 month period using the SF36 questionnaire
2. Level of bifidobacteria (a bacterium associated with gut health) in stool

Overall study start date
06/10/2014

Completion date
03/08/2015

Eligibility

Key inclusion criteria
1. Healthy male or female participants aged 18 years or above
2. In the opinion of the investigator, capable of complying with the study requirements and completing the study
3. Willing and able to give informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
16

Key exclusion criteria
Participants who have a current or previous history of gastrointestinal disease will not be eligible to take part in the study.

Date of first enrolment
01/04/2015

Date of final enrolment
01/08/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Wellcome Trust
1st Floor Wellcome Trust Building (Blue Zone)
Old Queen Elizabeth Hospital
Edgbaston
Birmingham
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B15 2TH

Sponsor information

Organisation
University of Birmingham

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Not defined

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/03/2019		Yes	No
HRA research summary			28/06/2023	No	No