

Alginate formulations for enhancing colonic health

Submission date 13/01/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/04/2019	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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?

1. Dr Chris Tselepis (scientific)

c.tselepis@bham.ac.uk

2. Dr Tariq Iqbal (public)

t.h.iqbal@bham.ac.uk

3. Mr Pritesh Mistry (public)

p.mistry.1@bham.ac.uk

Contact information

Type(s)

Public

Contact name

Dr Tariq Iqbal

Contact details

School of Cancer Sciences

Vincent Drive

University of Birmingham

Edgbaston

Birmingham

United Kingdom

B15 2TT

07713 575156

t.h.iqbal@bham.ac.uk

Type(s)

Scientific

Contact name

Dr Chris Tselepis

Contact details

School of Cancer Sciences
Vincent Drive
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 (0) 121 414 2972
c.tselepis@bham.ac.uk

Type(s)

Public

Contact name

Mr Pritesh Mistry

ORCID ID

<https://orcid.org/0000-0002-7066-0472>

Contact details

School of Cancer Sciences
Vincent Drive
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
0121 414 2228
p.mistry.1@bham.ac.uk

Additional identifiers**Protocol serial number**

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

Study type(s)

Quality of life

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(s)

General acceptability of Manucol LD by the end of the study period

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

Study participating centre**The Wellcome Trust**

1st Floor Wellcome Trust Building (Blue Zone)

Old Queen Elizabeth Hospital

Edgbaston

Birmingham

United Kingdom

B15 2TH

Sponsor information**Organisation**

University of Birmingham

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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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