# Alginate formulations for enhancing colonic health

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
13/01/2015		☐ Protocol		
Registration date 28/01/2015	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 08/04/2019	Condition category Digestive System	[] Individual participant data		
U0/U4/ZU19	Didestive 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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2. Dr Tariq Iqbal (public) t.h.iqbal@bham.ac.uk

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# Contact information

# Type(s)

Public

#### Contact name

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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 United Kingdom B15 2TH

# Sponsor information

# Organisation

University of Birmingham

# Sponsor details

The University of Birmingham
Edgbaston
Birmingham
England
United Kingdom
B15 2TT
0121 414 7618
researchgovernance@contacts.bham.ac.uk

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