

Prebiotics and immunity trial

Submission date 26/11/2010	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 26/11/2010	Overall study status Completed	☐ Protocol
Last Edited 09/12/2019	Condition category Haematological Disorders	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Philip Calder

Contact details

School of Medicine
IDS Building, Mail Point 887
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD
+44 23 8059 5000
pcc@soton.ac.uk

Additional identifiers

Protocol serial number

8280

Study information

Scientific Title

A placebo-controlled, double-blind, randomised study to evaluate the efficacy of fructo-oligosaccharides on the immune response in elderly people

Study objectives

Prebiotics may improve immune function in humans, but this is a poorly researched area. We will investigate the effect of short chain fructooligosaccharides on aspects of immune function, including response to seasonal influenza vaccination in healthy subjects aged over 65 years. The study will be randomised and controlled and the intervention period will be six weeks.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Isle of Wight, Portsmouth and South East Hampshire Research Ethics Committee, 02/03/2010, ref: 10/H0501/1

Primary study design

Interventional

Study design

Single-centre randomised interventional trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Inflammatory and Immune System, Primary Care Research Network for England; Subtopic: Not Assigned, Inflammatory and Immune System (all Subtopics); Disease: Immunology and inflammation, All Diseases

Interventions

Placebo: Maltodextrin, 4 g twice daily, 6 weeks, no follow-up beyond this

Active: Short-chain fructooligosachharide, 4 g twice daily, 6 weeks, no follow-up beyond this

Study entry: registration and one or more randomisations

Intervention Type

Drug

Phase

Phase I/II

Drug/device/biological/vaccine name(s)

Short-chain fructooligosaccharides

Primary outcome(s)

Serum anti-vaccine antibodies, measured at weeks 3 and 6 (0 and 3 weeks post-vaccination)

Key secondary outcome(s)

1. Blood immune cell subsets, measured at 0, 3 and 6 weeks
2. Ex vivo T-cell responses, measured at 0, 3 and 6 weeks
3. Faecal bacteria counts, measured at 0, 3 and 6 weeks
4. Salivary IgA, measured at 0, 3 and 6 weeks

Completion date

30/11/2010

Eligibility

Key inclusion criteria

1. Aged 65 years or older, either sex
2. In general good health
3. Body mass index 20 to 32 kg/m²
4. Not consuming probiotic supplements, yoghurts, drinks or other foods
5. Not consuming prebiotic supplemented drinks or foods
6. No antibiotic use in the 2 months prior to entering the study or during the study
7. Not already have received the 2010/2011 seasonal influenza vaccine
8. Willing to receive the seasonal influenza vaccination
9. Being able to provide written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Aged less than 65 years
2. Body mass index less than 20 or greater than 32 kg/m²
3. Being diabetic (type 1 or type 2)
4. Being egg allergic
5. Use of prescribed medicine to control inflammation or immune dysfunction
6. Chronic gastrointestinal problems (e.g. IBD, IBS, celiac disease, cancer)
7. Participation in another clinical trial
8. Use of prebiotic or probiotic supplements, foods or drinks
9. Consuming high-dose vitamin, mineral or fish oil supplements
10. Use of antibiotics within the previous two months
11. Previously vaccinated with the seasonal influenza vaccine

Date of first enrolment

06/09/2010

Date of final enrolment

30/11/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

School of Medicine

Southampton

United Kingdom

SO16 6YD

Sponsor information

Organisation

Southampton University Hospitals NHS Trust (UK)

ROR

<https://ror.org/0485axj58>

Funder(s)

Funder type

Industry

Funder Name

Beghin-Meiji (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration