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Prebiotics and immunity trial

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Study design
Single-centre randomised interventional trial

Primary study design
Interventional

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes