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Influence of soluble corn fibre on markers of immunity and inflammation

Submission date	**Recruitment status**	[X] Prospectively registered
15/02/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/02/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/06/2025	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

As people age their immune systems can become weaker and there is often an increase in inflammation which contributes to common age-related diseases. These include heart disease, metabolic disease such as type-2 diabetes, the loss of muscle mass and strength known as sarcopenia, the weakening of bones known as osteoporosis, some cancers, and possibly dementia. A weaker immune system means older people can be more susceptible to infections and some vaccines may not work as well as in younger adults. The “healthy” bacteria in the intestine (called gut microbiota) have an influence on the immune system and inflammation. Interestingly, intestinal bacteria also change with ageing and this can result in the loss of protective function and in the movement of harmful bacterial toxins and whole bacteria from the gut into the blood. Why these changes occur and how we can improve this in ageing are not understood. What we do know is that intestinal bacteria can be altered by diet. Fibre intake is considered essential for optimal gut health including maintaining healthy gut bacteria. However, most people do not eat enough fibre. We plan to investigate whether fibre supplements improve measures of the immune system, inflammation and intestinal bacteria in men and women aged over 60 years. The fibre we will use is called soluble corn fibre. This resists digestion and absorption in the small intestine and passes to the large intestine where it can be used by the gut microbiota. Soluble corn fibre has been shown to beneficially modify gut microbiota but its effects on the immune system and inflammation have not been tested. We plan to compare the effects of soluble corn fibre on the immune system and inflammation and gut microbiota with the effects of a placebo which is a poorly digested sugar called maltodextrin.

Who can participate?

Healthy men and women over the age of 60 years old

What does the study involve?

The study involves making two visits to the Clinical Research Facility at University Hospital Southampton. Each visit will last about 1.5 hours. In between visits participants will be randomly allocated to consume supplements of either placebo (maltodextrin) or soluble corn fibre each day for 12 weeks. At each clinic visit participants will be asked questions about their diet. They

will provide a blood sample for the measurement of immune and inflammatory markers. They will also provide a urine and faecal sample at the start and end of the study. In between visits, participants will be asked to keep a daily log to record the ingestion of their supplements.

What are the possible benefits and risks of participating?
Participants may benefit from positive effects on their immune system and//or their intestinal bacteria. Knowledge gained from the study will help research and will ultimately be of use to other researchers, industries and consumers. With any procedure involving blood collection with a needle, there is a very small chance of infection and a chance of bleeding and bruising at the site of insertion of the needle. This will be minimised by using sterile techniques and trained members of the staff.

Where is the study run from?
The University of Southampton (UK)

When is the study starting and how long is it expected to run for?
January 2021 to December 2025

Who is funding the study?
Tate & Lyle Plc (UK)

Who is the main contact?
Prof Philip Calder, pcc@soton.ac.uk (UK)

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
317212

Central Portfolio Management System (CPMS)
55174

Protocol serial number
76736

Study information

Scientific Title

Soluble corn fibre and markers of immunity and inflammation in older adults: a randomised controlled trial

Study objectives
The objective of this study is to identify the effects of soluble corn fibre, in the form of PROMITOR®, a Tate & Lyle product used in the food industry, on markers of immunity and inflammation and on faecal microbiota in older adults.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/12/2022, South Central - Hampshire A Research Ethics Committee (Temple Quay House, 2 The Square, Temple Quay, Bristol BS1 6PN, UK; +44 (0)207 104 8196; hampshirea.rec@hra.nhs.uk), ref: 22/SC/0414

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
People aged 60 + years living in the community

Interventions
Participants will be sought through poster advertisements; articles in the media (newsletters, newspapers, radio, and university project-specific social media pages); posters and email within the University of Southampton and University Hospital Southampton NHS Foundation Trust; and by contacting those on a GDPR compliant database held by the University Hospital Southampton. The study involves making two visits to the Clinical Research Facility at University Hospital Southampton, one at study entry and the second 12 weeks later. Each visit will last about 1.5 hours.

Participants will be randomly allocated IDs according to a random number generator for a two-arm study to two treatment groups to consume control (maltodextrin 2 g/day - calorie matched to soluble corn fibre) and soluble corn fibre (20 g/day) for 12 weeks in between study visits.

At each clinic visit participants will be asked questions about their diet. They will provide a blood sample for the measurement of immune and inflammatory markers. They will also provide a urine and faecal sample at the start and end of the study. In between visits, participants will be asked to keep a daily log to record the ingestion of their supplements.

Intervention Type
Supplement

Primary outcome(s)

Blood neutrophil phagocytosis of E. coli measured as median fluorescence intensity using flow cytometry, reflecting the number of bacteria taken up per neutrophil, at study entry and exit (week 12)

Key secondary outcome(s)
All secondary outcomes are assessed at study entry and exit (12 weeks)
1. Blood immune cell phenotypes (number of each cell type per microlitre of blood) measured by flow cytometry
2. Plasma inflammatory cytokines and chemokines (mg/l) measured by multiplex immunoassay
3. Plasma C-reactive protein (mg/l) measured by immunoassay
4. Blood monocyte phagocytosis of E. coli measured as median fluorescence intensity by flow cytometry
5. Blood natural killer cell activity measured as % killing to K562 target cells by flow cytometry
6. Blood T cell response to stimulation with Con A measured as CD69 expression (flow cytometry) and immunoregulatory cytokine production (multiplex immunoassay)
7. Blood monocyte response to stimulation with LPS measured as immunoregulatory cytokine production (multiplex immunoassay)
8. Faecal microbiota measured as the numbers of different organisms/g faeces by 16S RNA sequencing
9. Faecal short-chain fatty acid concentrations (mmol/l) measured by gas chromatography
10 Faecal calprotectin and intestinal fatty acid binding protein (mg/l) measured by immunoassay
11. Plasma short-chain fatty acids (mmol/l) measured by gas chromatography
12. Urinary metabolome measured by nuclear magnetic resonance
13. Gastrointestinal health measured by questionnaire and Bristol Stool Chart score
14. Energy (cal/day) and macronutrient (g/day) intake measured by a food frequency questionnaire (FFQ)

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Community-dwelling males and females aged 60 years and older
2. Body mass index of 18.5-30 kg/m2
3. Have regular bowel movements
4. Willing to adhere to the study protocol
5. Able to provide written informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
60 Years

Sex
All

Total final enrolment
72

Key exclusion criteria
1. Living in a care or nursing home
2. Diagnosed with diabetes or other metabolic and endocrine disorders
3. Presence of active gastrointestinal disease (coeliac disease, Crohn's disease, diagnosed IBD etc.), autoimmune disease, or inflammatory disease (lupus, rheumatoid arthritis, multiple sclerosis)
4. Use of prescribed medicine to control inflammation (e.g. non-steroidal anti-inflammatory drugs; NSAIDs) or regular use of over-the-counter NSAIDs
5. Use of dietary supplements (will allow a 4-week washout period)
6. Use of probiotic drinks or yoghurts (will allow a 4-week washout period)
7. Have extreme habitual fibre intake (lower than 10 g per day or higher than 30 g per day) based on a validated fibre screening tool
8. Blood donation in the previous 3 months.
9. Participation in any other clinical trial in the previous 3 months

Date of first enrolment
01/03/2023

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton
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Sponsor information

Organisation

University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Industry

Funder Name
Tate & Lyle Plc

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	version 4.0	03/02/2023	17/02/2023	No	Yes
Protocol file	version 3.0	10/02/2023	17/02/2023	No	No