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Carrageenan in ulcerative colitis

Submission date 19/10/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 25/10/2021	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 13/02/2025	**Condition category** Digestive System	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Carrageenan is a common food additive extracted from red seaweed. It may cause increased immune activity and colitis (inflammation in the large bowel). However, carrageenan is approved for use by the European Food Safety Authority (EFSA) and US Food and Drug Administration (FDA) and is consumed regularly by Western populations. While some data from animal tests suggest that carrageenan is proinflammatory, there is only very limited data in humans. The aim of this study is to find out whether food-grade carrageenan causes gastrointestinal (digestive) symptoms, inflammation and hyperpermeability (leaky gut) in patients with ulcerative colitis when consumed at a high normal level according to the EU standard population.

Who can participate?
Patients aged 18-64 years with ulcerative colitis which is in clinical remission (no symptoms)

What does the study involve?
The study starts with a 7-day run-in period where participants consume a low carrageenan diet, as instructed by a dietician, then the participants are randomly allocated to consume either 2-2.5 g per day of carrageenan or a corresponding dose of oat fiber for 7 days, followed by at least 14 days break (may be slightly longer for some if the 14-day period is not possible for practical reasons), then the other treatment (either carrageenan or oat fiber) for 7 days.

What are the possible benefits and risks of participating?
The participants will get detailed information on their gut health, will help to progress science on gastrointestinal health and nutrition, and will also will get an appointment with a dietician for free after the study is finished. The potential risks to the participants include mild gastrointestinal symptoms and minor pain during the blood tests and mild bruising of the forearm after the blood tests.

Where is the study run from?
Selex Lab (Finland)

When is the study starting and how long is it expected to run for?
January 2021 to December 2022

Who is funding the study?
BoostOn Oy Ltd (Finland)

Who is the main contact?
Dr Reijo Laatikainen
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
HUS/770/2021

Study information

Scientific Title
Carrageenan in ulcerative colitis: a randomised controlled trial

Acronym
CARRAUC

Study objectives
Carrageenan may cause immune activation in ulcerative colitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/04/2021, Helsinki and Uusimaa Hospital District Ethics Committee II (HUS Central Registry Office, Marjaniementie 74, Iiris Center, 00930, Helsinki, Finland; +358 (0)50 428 7386; anna.pallari@hus.fi), ref: HUS/770/2021

Primary study design
Interventional

Study design
Randomized controlled cross-over trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ulcerative colitis

Interventions
Carrageenan 2-2.5 g/day vs oat fiber, corresponding dose

The study starts with a 7-day run-in period (low carrageenan diet, instructed by a dietician), then either a carrageenan period or an oat fiber (control) period for 7 days, followed by at least 14 days' washout (may be slightly longer for some if the 14-day period is not possible for practical reasons), then after the washout the other treatment (either carrageenan or control). This makes altogether 35 days including one run-in period, one washout period and two treatment periods.

Randomisation: generated by an automated computer service (https://www.sealedenvelope.com /simple-randomiser/v1/lists) in blocks of four.

Intervention Type
Supplement

Primary outcome(s)
Colitis activity measured using the Simple Clinical Colitis Assessment Index (SCCAI) at baseline and the 7th day of both treatment periods

Key secondary outcome(s)
1. Gastrointestinal symptoms measured by Visual Analog Scale (VAS) 0-100 at baseline and the 1st, 3rd and 7th day of both treatment periods at the end of the each day
2. Laboratory tests using blood, urine and stool samples at baseline and at the end (7th day) of both treatment periods:
2.1. Fecal calprotectin
2.2. hs-CRP
2.3. S-FABP-2 (intestinal permeability marker)
2.4. U-creatinine
2.5. U-Albumin
2.6. F-albumin
2.7. F-IgG
2.8. F-intestinal alkaline phosphatase (IAP)
3. Macronutrient and fiber intake measured using a food diary at the end of both treatment periods covering days 5, 6 and 7 (i.e. a 3-day food diary)

Completion date
01/12/2022

Eligibility

Key inclusion criteria
1. Ulcerative colitis, clinical remission verified by normal fecal calprotectin
2. Aged 18-64 years
3. No biological medications or systemic cortisone usage for relapse

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
All

Total final enrolment
8

Key exclusion criteria
1. Pregnancy/lactation
2. Currently participating in another clinical intervention study
3. Intestinal surgery
4. Cancer
5. Other severe illness which might affect the patient's ability to participate in the study

Date of first enrolment
23/08/2021

Date of final enrolment
01/05/2022

Locations

Countries of recruitment
Finland

Study participating centre

Selex Lab
Kalavankatu 17
Helsinki
Finland
00100

Sponsor information

Organisation
Juhani Aho Medical Research Foundation

Funder(s)

Funder type
Industry

Funder Name
BoostOn Oy Ltd

Results and Publications

Individual participant data (IPD) sharing plan
Patient-level data available upon reasonable request from Dr Reijo Laatikainen (reijo.laatikainen@booston.fi)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/10/2023	13/02/2025	Yes	No
Protocol file	version 2	30/03/2021	10/08/2022	No	No