

# Carrageenan in ulcerative colitis

<b>Submission date</b> 19/10/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/10/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/02/2025	<b>Condition category</b> Digestive System	<input type="checkbox"/> 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  
reijo.laatikainen@booston.fi

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Reijo Laatikainen

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**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

## **Study design**

Randomized controlled cross-over trial

## **Primary study design**

Interventional

## **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?
<a href="#">Results article</a>		30/10/2023	13/02/2025	Yes	No
<a href="#">Protocol file</a>	version 2	30/03/2021	10/08/2022	No	No