ISRCTN64064335 https://doi.org/10.1186/ISRCTN64064335

The effect of a dairy protein hydrolysate on gut health in an inflammatory bowel disease population

Submission date 11/08/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 21/09/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/08/2026	**Condition category** Digestive System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Inflammatory bowel disease (IBD) is characterised by chronic gastrointestinal symptoms (bloating, constipation, blood in stool), which are caused by inflammation in the gut and an imbalance in the gut microbiome (bacteria in the gut). IBD affects many people worldwide and while the disease can be managed through medication, there is no absolute cure. Dietary approaches are important to help ease symptoms in IBD patients. Certain dairy supplements, such as dairy protein derivatives (e.g., casein hydrolysate) may help to improve symptoms in IBD patients. This study aims to understand how supplementation of a casein hydrolysate can potentially improve gut health in an IBD cohort.

Who can participate?
Patients aged over 18 years with IBD in remission (non-active disease)

What does the study involve?
Participants will be randomly assigned to either the intervention group (casein hydrolysate) or the control group (maltodextrin) and will consume 4 g/d of either the casein hydrolysate or the control, for 6 weeks. Participants will come into the St Vincent's University Hospital Gastroenterology Research Unit for two study visits - one at week 0 (baseline) and one at week 6 (post-intervention). During these study visits a range of biological (bloods, faecal) and non-biological (weight, height, quality of life questionnaires) data will be collected.

What are the possible benefits and risks of participating?
There are no direct benefits of participating, although patients will be contributing to important IBD research. There are minimal risks of participating, although it is possible that the casein supplement or maltodextrin supplement may cause gastrointestinal discomfort among IBD patients (certain foods can trigger symptoms in certain people). Participants will be monitored during the study through email and phone calls to assess this, and they are free to drop-out at any time if they wish.

Where is the study run from?
St Vincent's University Hospital (Ireland)

When is the study starting and how long is it expected to run for?
February 2022 to November 2022

Who is funding the study?
Food for Health Ireland, funded by Enterprise Ireland

Who is the main contact?
1. Prof. Glen Doherty, glen.doherty@ucd.ie
2. Dr Cliona Ni Chonnachain, cliona.nichonnachain@ucd.ie

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
The effects of casein hydrolysate supplementation on the gut microbiome and gastrointestinal health in an ulcerative colitis cohort: a randomised controlled pilot study

Study objectives
To determine the effects of dietary supplementation with a casein hydrolysate (UL-2-132) on parameters of the gut microbiota and quality of life in a UC cohort.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 15/01/2021, Research Ethics Committee, St Vincent's University Hospital (Research Ethics Department Education & Research Centre St. Vincent’s University Hospital, Elm Park, Dublin 4, Dublin, D04T6F4, Ireland; +353 (01) 221 4000; svhgethics@ucd.ie), ref: RS20-065

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Basic science, Supportive care

Study type(s)

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

Interventions
A random number generator was used for randomisation. Participants meeting inclusion criteria were randomly assigned to the intervention group (casein hydrolysate UL-2-132) or control group (maltodextrin) on a 1:1 ratio, determined by a random number generator.

Intervention arm: 4 g/day of a casein hydrolysate for 6 weeks
Control arm: 4 g/day of a maltodextrin control for 6 weeks

Intervention Type
Supplement

Primary outcome(s)
1. Gut microbiome abundance and diversity measured using metagenomic sequencing, bioinformatic and statistical analysis at baseline (week 0) and post-intervention (week 6)

Key secondary outcome(s)
1. Quality of life measured using the Short Inflammatory Bowel Disease Questionnaire (SIBDQ), the Short Health Scale (SHS), and the GI Quality of Life Index-10 (GIQLI-10) at baseline (week 0) and post-intervention (week 6)

Completion date
25/11/2022

Eligibility

Key inclusion criteria
1. Ulcerative colitis (UC) patients in remission (faecal calprotectin <100 ug/g)
2. >18 years of age

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
33

Key exclusion criteria
1. <18 years old
2. Escalation of medical therapy within 3 months prior to the study
3. Inability to provide written informed consent
4. Pregnant or breastfeeding women
5. Dairy allergy
6. Significant comorbid physical or mental health conditions
7. Recent antibiotic or probiotic use (within 3 weeks)
8. Recent or planned exclusion diet or major dietary modification (within 3 months)

Date of first enrolment
22/02/2022

Date of final enrolment
10/10/2022

Locations

Countries of recruitment
Ireland

Sponsor information

Organisation

Food for Health Ireland

ROR
https://ror.org/01nvbq395

Funder(s)

Funder type

Funder Name
Enterprise Ireland

Alternative Name(s)
The Enterprise Ireland

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			11/08/2026	No	Yes