Participant Information Sheet

Bile Acid Malabsorption (BAM) study

Study Title	**Bile acid sequestrant response and symptom changes in adults with chronic diarrhoea**
Principal Investigator	Dr Simone Bayer
Study site	University of Otago, Christchurch
Contact phone number	021 279 1519
Email	gastrointestinal.research@otago.ac.nz
Ethics committee ref	2025-Full-24140

INVITATION

You are invited to take part in a study on chronic diarrhoea. Participation is completely voluntary. You can withdraw at any time without affecting your medical care.

This document explains the study so you can decide if you'd like to participate. Please read it carefully. You can discuss it with whānau, friends, or your doctor before deciding. We will answer any questions you have.

This document is 10 pages long, including the consent form.

WHAT IS THE PURPOSE OF THE STUDY?

Bile acid malabsorption (BAM) is a condition where the body cannot reabsorb bile acids properly. This causes chronic diarrhoea and abdominal pain. Many people with chronic diarrhoea may have undiagnosed BAM because there is no test available in New Zealand.

We are trying to:

- Find out how common BAM is in people with chronic diarrhoea
- Test whether a simple blood test can diagnose BAM
- Learn how well people respond to the BAM medication (cholestyramine)

Cholestyramine is prescribed under Section 29 of the Medicines Act 1981 in New Zealand, as they are not currently approved by Medsafe for the treatment of bile acid malabsorption or chronic diarrhoea. However, cholestyramine is recommended in European and US clinical guidelines for the management of IBS-D and suspected bile acid malabsorption.

This is the first study of BAM in adults with chronic diarrhoea in New Zealand.

The study protocol has been reviewed and approved by: HDEC,

WHAT WOULD I DO?

Study duration: 3 weeks/ 21 days total, with 2 clinic visits

Screening Visit (approximately 60 minutes)

Location: University of Otago Christchurch research clinic, Christchurch Hospital

- Fast for 9 hours beforehand (usually overnight)
- Sign consent and check eligibility
- Blood test (16 mL)
- Receive study instructions
- Receive $20 MTA or Pack'n'Safe voucher

We review your blood test results (takes 2-3 days). If you are eligible, we contact you to start the study and send you a prescription for the medication (Cholestyramine). If any results need medical follow-up, we'll let you know and recommend seeing your GP.

Days 1-7: Baseline Monitoring Week (no medication)

If you don't have internet or a smartphone: We provide paper versions of everything. You can post them back or we can collect them.

Daily bowel diary (online or paper):

- Takes 1-2 minutes per day
- Record number of bowel movements and stool consistency using Bristol Stool Scale (a simple picture chart)
- Record urgency and any discomfort

Day 7 Gastrointestinal Symptom Rating Scale (GSRS, online or paper): 15 questions about your gut symptoms (5-10 minutes)

- **Day 7 - 21 Treatment Period (14 days)**

- You begin taking cholestyramine (Questran Lite) daily
- Continue daily bowel diary until the end of the study to a total of 21 days
- Fill out side-effect checklist

How to take it:

- Mix one sachet (powder) with water, juice, or soft food like yogurt
- Take in morning OR evening (your choice) - same time each day
- Take at least 4 hours before OR 1 hours after any other medications. **The exception are oral contraceptives; these should be taken 4 hours before cholestyramine.**
- Start with 1 sachet/day, may increase to 3 sachets/day
- You control the dose based on how you feel - increase gradually or stay at 1 sachet if that works for you. Do not exceed 3 sachets/day.

Support during medication period:

- We give you detailed written instructions
- You can call or email us anytime with questions (021 279 1519)

Day 21: End-of-Study Visit (30-45 minutes)

Location: University of Otago Christchurch research clinic

- Fast for 9 hours beforehand
- Blood test (6 mL)
- Complete final questionnaire
- Return unused medication
- Receive $30 MTA or Pack'n'safe voucher

After study completion:

We send you a summary of your results including:

- Whether you responded to the medication
- Recommendation to discuss with your GP if medication helped
- Your BAM biomarker levels (with explanation, may take up to 1 year)
- If medication helped, your GP can prescribe it for ongoing use

Summary Timeline

When	What You Do	Where	Time
Screening	Blood test, consent, eligibility check questionnaire	Clinic visit	60 min
Days 1-21	Daily bowel diary	At home	1-2 min/day
Day 7	Day 7 questionnaire	At home	5 minutes
Days 7-21	Take medication, daily diary, side-effect checklist	At home	10 min/day
Day 21	Blood test, final questionnaires, return medication	Clinic visit	30-45 min
After study	Receive results summary	Email/post	-

Total time commitment: Approximately 4 hours spread over 21 days

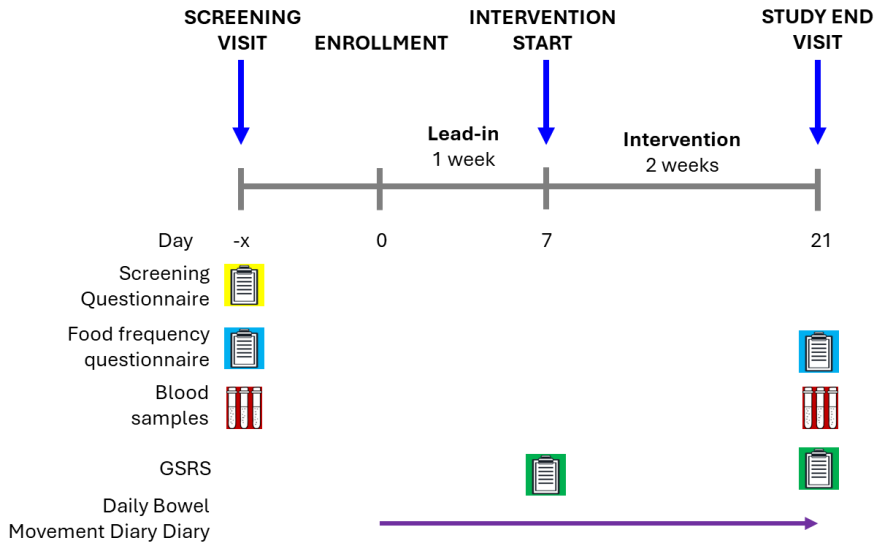

Figure: Study overview and timeline

WHO CAN PARTICIPATE?

You may be eligible if you:

- Are 18 or older
- Have chronic diarrhoea (3+ months) with loose stools, urgency, or abdominal pain
- Can complete daily diaries

You cannot participate if you:

- Have bowel disease (IBD, coeliac, cancer)
- Are already taking bile acid medication
- Are pregnant/breastfeeding
- Take certain medications (warfarin, digoxin)
- Have had major bowel surgery

We will check your full eligibility at screening

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

Cholestyramine side effects:

How Common	Side Effects
Very common (>1 in 10)	Constipation
Common (up to 1 in 10)	Nausea, gas, bloating, abdominal cramps, heartburn
Less common	Vomiting, headache, decreased appetite, intestinal obstruction

Most side effects are mild. You can reduce your dose or stop anytime. Because you only take it for 14 days, long-term effects are not expected.

However, severe constipation can lead to intestinal obstruction in vulnerable individuals, making it a rare but serious risk.

What to do: Contact us if side effects bother you, especially constipation (021 279 1519). Stop immediately if severe.

Blood test risks:

- Common: Brief pain, bruising, throbbing
- Uncommon: Fainting, light-headedness
- Rare: Excessive bleeding, infection

Fasting risks:

- Hunger, queasiness, light-headedness, headache
- Minimized by morning appointments and providing snacks after blood tests

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

For you:

- Find out if you have BAM
- If medication helps, your GP can continue prescribing it
- Receive your blood test results
- $20 MTA or Pack'n'Safe voucher at the screening visit and a $30 MTA or Pack'n'Safe voucher at follow up to thank you for your participation and to cover travel cost and prescription fee ($50 in total).

No guarantee the medication will help your symptoms.

For others:

- Help develop a simple diagnostic test for BAM
- Provide first NZ data on BAM prevalence
- Improve care for people with chronic diarrhoea

WHAT HAPPENS TO MY BLOOD SAMPLE?

- Volume: 16 mL at the screening visit, 6ml at the follow up visit
- Tests: General health (screening only, 10ml) and BAM biomarkers (C4, FGF19, INSL5, 6 ml)
- Where analysed: Canterbury Health Laboratories, Christchurch
- Storage: Samples destroyed during analysis; any leftover disposed of within 5 years
- Not sent overseas or kept for future research

Cultural considerations:

You may hold beliefs about the sacred value of samples. Please discuss with whānau. Some iwi advise consultation before participating in research involving sample storage.

We have been gifted a karakia to use before processing samples. If you'd like this, please tick the box on the consent form.

WHAT HAPPENS TO MY INFORMATION?

Your identifiable information (name, contact details):

- Accessible only to research team and your GP (with consent)
- Stored securely at University of Otago for 10 years, then destroyed

Your study data (questionnaires, test results):

- Identified by code number only
- Stored in secure database (REDCap, NZ servers) at University of Otago for 10 years, then destroyed
- Not sent overseas
- Used only for this study
- Published in anonymised form

Your rights:

- Access your information anytime
- Withdraw consent anytime (data collected until withdrawal will be kept unless you request deletion)
- Request corrections to your information

COSTS AND COMPENSATION

- **Participation costs:** There is no cost to you to participate in this study. All blood tests are provided free of charge.
- **Study medication:** You will receive a prescription for cholestyramine (Questran Lite). Standard prescription charges apply as set by the New Zealand Government ($5 per item, or free if you have a Community Services Card or visit bargain Chemist/

Chemist Warehouse or are exempt from prescription charges). This is the same cost you would pay for any prescription from your GP/Gastroenterologist.

- **After the study:** If cholestyramine helps your symptoms and you wish to continue taking it, your GP can prescribe it. Standard prescription charges will apply.
- **Compensation:** You will receive $50 vouchers in total ($20 at screening and $30 at Day 21) to thank you for your time, and to cover prescription fee and travel costs. You will receive this voucher regardless of whether you complete the full study, as long as you attend each visit.

WHO FUNDS THIS?

This study is funded by a Janssen Fellowship Award, New Zealand Society for Gastroenterology. The funder has no role in study conduct or results.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

Research team:

Dr Simone Bayer, Trainee and RA TBA

021 279 1519 | gastrointestinal.research@otago.ac.nz

Independent advocate:

0800 555 050 | advocacy@hdc.org.nz | www.advocacy.org.nz

Māori health support:

Ngā Ratonga Hauora, Christchurch Hospital | 03 364 0640 (Ext 86160)

HDEC:

hdecs@health.govt.nz | 0800 400 569 (Ministry of Health)

Consent Form

Bile Acid Malabsorption (BAM) Study

Please tick each box:

☐ I have read and understand the Participant Information Sheet

☐ I have had enough time to consider participation and ask questions

☐ I had opportunity to discuss with whānau/family/friends

☐ I am satisfied with answers given and have a copy of this document

☐ I understand participation is voluntary and I can withdraw anytime

☐ I consent to collection of my health information for this study

☐ I understand my information will NOT be sent overseas

☐ If I withdraw, prior collected information may be kept (unless I request deletion)

☐ I consent to my GP being informed of my participation and significant results

☐ I consent to blood sample collection, storage at Canterbury Health Labs, and disposal within 5 years

☐ **I would like karakia performed before my samples are processed** (optional)

☐ I consent to authorized auditors reviewing my medical records to verify study data

☐ I understand my participation is confidential and no identifying information will be published

☐ I understand compensation provisions if injured

☐ I know who to contact with questions

☐ I understand my responsibilities (take medication, complete diaries, attend visits)

☐ **I wish to receive a summary of study results: YES / NO**

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature:	Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it. I believe that the participant understands the study and has given informed consent to take part.

Researcher's Name:

Signature:	Date: