MONASH University

EXPLANATORY STATEMENT

Project ID: 38778
Project title: Exploring the tolerability of nutritive and non-nutritive sweeteners in people with irritable bowel syndrome.

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You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

What does the research involve?

In this study we are examining how well different sweeteners are tolerated in healthy volunteers and people with irritable bowel syndrome (IBS).

To be eligible to participate in this study, you must meet the following inclusion and exclusion criteria.
Inclusion criteria

- Healthy volunteer (no irritable bowel syndrome and not meeting exclusion criteria)

OR

- Irritable bowel syndrome and symptoms well controlled on a low FODMAP diet.

Exclusion criteria

- Age under 18 years
- Recent gastrointestinal surgery (within last 3 months)
- Coeliac disease and/or other gastrointestinal disease, food allergy/intolerances, malnutrition, other dietary restrictions (e.g. vegan or vegetarian)
- Pregnancy or breastfeeding
- Active psychological illness including eating disorders
- People living outside of metro-Melbourne
- Smoker – vapes or tobacco

Participants are required to sign an electronic consent form before starting the study. The sweeteners being examined in this study are erythritol, monk fruit extract, stevia, allulose or sucrose. Erythritol is a sugar alcohol that provides around half the energy of sucrose (table sugar). By contrast, monk fruit extract, stevia and allulose contain zero or very low amounts of carbohydrates or energy and are considered more 'natural' types of sweeteners. Sucrose is also known as table sugar and is known to be well tolerated in healthy people and people with IBS. Therefore, we are comparing the tolerability of erythritol, monk fruit extract, stevia and allulose with a sweetener known to be well tolerated - sucrose.

This dietary study will require you to eat particular foods, record your food intake, collect breath hydrogen samples and complete symptom questionnaires. Breath test samples will be collected from your house within 14 days of collection. You are encouraged to eat according to the meal plan for the duration of the baseline and test periods. However, if you are hungry, you will be supplied a list of suitable 'extra foods' that you may purchase and consume. The protocol involves the following:

Timepoint	What is involved	Time commitment
Baseline (1 day) (Day 1)	• Consume a low FODMAP diet (not supplied) • Complete a daily food diary • Complete a daily symptom questionnaire • Collect hourly breath samples from 8am to 7pm	• Food diary - 10 minutes • Symptom diary - 10 minutes • Breath samples - 1 hour
Test period 1 (2 days) (Days 2-3)	• Consume a semi-supplied low FODMAP diet, including 2 test food/drinks per day • Complete a daily food diary • Complete a daily symptom questionnaire • On the 2nd day (day 3), collect hourly breath samples from 8am to 7pm	• Food diary - 10 minutes/day • Symptom diary - 10 minutes/day • Breath samples - 1 hour total
Washout (5 days) (Days 4-8)	• Return to low FODMAP diet (not supplied).	Nil
Test period 2 (2 days) (Days 9-10)	• Consume a semi-supplied low FODMAP diet, including 2 test food/drinks per day • Complete a daily food diary • Complete a daily symptom questionnaire	• Food diary - 10 minutes/day • Symptom diary - 10 minutes/day • Breath samples - 1 hour total

	● On the 2nd day (day 10), collect hourly breath samples from 8am to 7pm	
Washout (5 days) (Days 11-15)	● Return to a low FODMAP diet (not supplied).	Nil
Test period 3 (2 days) (Days 16-17)	● Consume a semi-supplied low FODMAP diet, including 2 test food/drinks ● Complete a daily food diary ● Complete a daily symptom questionnaire ● On the 2nd day (day 17), collect hourly breath samples from 8am to 7pm	● Food diary - 10 minutes/day ● Symptom diary - 10 minutes/day ● Breath samples - 1 hour total
Washout (5 days) (days 18-22)	● Return to a low FODMAP diet (not supplied).	Nil
Test period 4 (2 days) **(Days 23-24)**	● Consume a semi-supplied low FODMAP diet, including 2 test food/drinks ● Complete a daily food diary ● Complete a daily symptom questionnaire ● On the 2nd day (day 24), collect hourly breath samples from 8am to 7pm only).	● Food diary - 10 minutes/day ● Symptom diary - 10 minutes/day ● Breath samples - 1 hour total
Washout (5 days) Days 25-29	● Return to a low FODMAP diet (not supplied).	Nil
Test period 5 (2 days) (Days 30-31)	● Consume a semi-supplied low FODMAP diet, including 2 test food/drinks ● Complete a daily food diary ● Complete a daily symptom questionnaire ● On the 2nd day (day 31), collect hourly breath samples from 8am to 7pm only).	● Food diary - 10 minutes/day ● Symptom diary - 10 minutes/day ● Breath samples - 1 hour total

Why were you invited for this research?

You were invited for this research because you told us that you are either a healthy volunteer or because you have a diagnosis of IBS with symptoms that are currently well controlled on a low FODMAP diet.

Source of funding

The project is part funded by a certification partner of the Monash FODMAP Team - Modify Health. Modify Health produces ready-made meals that are low in FODMAPs and suitable for people with irritable bowel syndrome (IBS).

Consenting to participate in the project and withdrawing from the research

Participation in this research is voluntary. If you do not wish to take part you do not have to, and your decisions will not affect your routine treatment, your relationship with those treating you or your relationship with Monash University and the Alfred Centre. If you decide you wish to take part, you will be asked to sign the consent form. By signing the consent form you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to do the tests and follow dietary recommendations
- Consent to the use of your personal and health information as described.

You will be able to download a copy of this explanatory statement and consent form to keep.

You may withdraw from this project at any stage. Please let the study coordinator know so they can discuss any issues that may arise from you withdrawing, and can answer any questions you may have. If you do withdraw your consent, no additional data will be asked of you. If you withdraw from the study within 2 weeks of commencing the protocol, you may choose to withdraw your data also. Please contact the study co-ordinator (Dr Jane Varney) if you wish to withdraw from the study and to withdraw your data. If you withdraw from the study after 2 weeks of commencing the study protocol, personal information already collected will be retained to ensure the results of the study are recorded properly and to comply with the law as we need to retain data (medical events, age, medications, medical history etc) to ensure correct reporting for the trial.

Possible benefits and risks to participants

The benefits of participating in this study include being provided some food for your meals and snacks during the baseline and test periods. Benefits to the community of this study are increasing understanding whether or not the sweeteners in question are tolerated in people with IBS. This information could help in the development of food and beverage products that are better tolerated by consumers with and/or without IBS.

Anticipated risks may include a possible increase in GI symptoms from the supplied diet that is different to what you normally eat. Should you be troubled by this, please contact the study coordinator.

You may also be inconvenienced by having to collect the data required for this study (e.g. breath samples, symptom questionnaires, food diaries).

Although it is very unlikely that an adverse event will occur, if you do experience an adverse reaction to the study diet please stop the diet immediately and contact the study coordinator. The study coordinator will advise you on what to do. Contact details are at the beginning of this information sheet.

Services on offer if adversely affected

We do not anticipate you will become upset or distressed as a result of your participation in the research. However, if you do, we will arrange a referral to an external mental health care provider that is not part of the research project team. You may choose to access this through your GP where costs may be offset by the use of a mental healthcare plan that allows medicare reimbursement of costs". Alternatively, you can access one of the following services:

- Nurse on Call - A Victorian Government health initiative, is a phone service that provides immediate, health advice and information from a registered nurse, 24 hours a day, 7 days a week. Telephone 1300 606 024
- Beyond Blue offers access to information, resources and services www.beyondblue.org
- Lifeline - offers confidential counselling and referrals, 24 hours a day, 7 days a week. Telephone 13 11 14

Confidentiality

You will sign your consent form and complete some study questionnaires on REDcap. Redcap is a forum for online questionnaires that is totally confidential. Only people licensed to access it can see your answers. These people will be the study coordinator and the chief investigator named above.

Any identifying information obtained in connection with this research project, including information collected in the screening questionnaire will remain confidential and securely stored. All data pertaining to you will be allocated a

study number or code, which can be re-identified if needed at any stage of the study. It will be disclosed only with your permission, or as required by law. All data will be stored in a password protected server (that only the listed investigators have access to) in the Department of Gastroenterology, Monash University. This information is stored for 7 years after publication of the results. After this time, digital data will be deleted.

All breath samples will be processed immediately and then destroyed.

It is anticipated that the results of this research project will be published and/or presented in scientific seminars and conferences. In any publication or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Only combined data from which no individual can ever be identified will be published. You will be advised of the results of the research study when the data have been analysed and prepared for publication. This can take months to years after the project has finished.

In accordance with data sharing guidelines, de-identified data may be made available for use by the other researchers. This data will be held on secure public repositories and may be a requirement of some journals prior to publication. Any shared data will not include your identifying details.

Results

It is anticipated that the results of this research project will be published and/or presented in scientific seminars and conferences. In any publication or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Only combined data from which no individual can ever be identified will be published. You will be advised of the results of the research study when the data have been analysed and prepared for publication. This can take months to years after the project has finished.

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Chancellery Building D,
26 Sports Walk, Clayton Campus
Research Office
Monash University VIC 3800

Tel: +61 3 9905 2052 Email: muhrec@monash.edu Fax: +61 3 9905 3831

Thank you,
Dr Jane Varney