PARTICIPANT INFORMATION SHEET

Effect of Fucoidan on glucose control and markers of cardiometabolic health after chronic dosing

Invitation
You are invited to participate in a research study analysing the effect on blood sugar levels after consuming **Maritech® Synergy which is manufactured by Marinova Pty Ltd**. It is a seaweed extract primarily made up of high purity fucoidan, which has been found to play a role in maintaining healthy blood sugar levels.

The study is being conducted by Cameron Wright (researcher) and Woldesellassie Bezabhe (PhD candidate), both from the Division of Pharmacy at the University of Tasmania. The other researchers are:

- Professor Gregory Peterson, Professor of Pharmacy, School of Pharmacy UTAS
- Dr Luke Bereznicki, Acting Head of School and Senior Lecturer in Pharmacy Practice, School of Pharmacy UTAS
- Dr Rahul Patel, Lecturer/ Library Liaison, School of Pharmacy UTAS
- Dr Leanne Chalmers, Lecturer in Clinical Pharmacy, School of Pharmacy UTAS
- J Helen Fitton, Senior Scientist, Marinova Pty Ltd
- Dr. Damien Stringer, Product Development Manager, Marinova Pty Ltd

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. ‘What is the purpose of this study?’
The purpose is to investigate whether ingestion of a commercially available fucoidan/polyphloroglucinol extract (Maritech® Synergy) over a 3 month period has any effect on your cholesterol and insulin levels, and also on your blood sugar levels following consumption of a sucrose drink.

2. ‘Why have I been invited to participate in this study?’
You are eligible to participate in this study because you have been identified as fitting the specific criteria of the study, which are;

   - Age Range: 18-65
   - Body mass index (BMI): ≥30 kg/m² (calculated on screening)
   - Not a current smoker.
   - Not taking > 5 regular medications
Not taking regular anticoagulant medications (other than low dose aspirin) or have any contraindication to anticoagulant medications
No history of diabetes.
Random glucose level <7.8 mmol/L (tested on screening)

If your random blood glucose level is found to be > 7.8 mmol/L on screening, or if your fasting blood glucose level is > 7 mmol/L on the study visits, you will be informed by the researchers and referred to your GP for further investigation.

3. ‘What if I don’t want to take part in this study, or if I want to withdraw later?’
Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason. However, it may not be possible to return your samples to you or withdraw your data from the study results if these have already had your identifying details removed.

4. ‘What does this study involve?’
If you agree to participate in this study, you will be asked to sign the Participant Consent Form. You will then be screened for your eligibility for the study, which will involve a height, waist circumference and weight measurement for BMI calculation and a random blood sugar level test. This will take approximately 10 minutes and can be done at an agreed time between you and the researchers.

If you are eligible to participate in the study, you will then be required to:

- Take a twice daily 500 mg dose of Maritech® Synergy manufactured by Marinova Pty Ltd or placebo over a 3 month period. Allocation to either group is by chance (randomly).
- Visit the University on two separate occasions over the 3 month period of the study, with these visits occurring at the beginning and end of the study and taking approximately 3 hours each.
- Fast overnight on two separate occasions, which will occur the night before each university visit
- Have your height, weight and blood pressure measured at each university visit
- Have a venous blood sample taken by a trained technician at each visit, which will later be analysed for insulin, HbA1c, and blood lipids. A sub-sample of this blood will also be securely kept in a freezer within the School of Pharmacy, University of Tasmania, for later analysis of fucoidan.
• At each visit, take a sucrose (sugar-based) drink, followed by blood-sugar testing over a 2 hour period at intervals of 0, 10, 20, 30, 45, 60, 90, 120 mins. A sample of blood will be taken at each time point (8 samples in total) from your fingertip by the finger prick technique and then analysed for blood glucose.

Exclusion criteria for the study are:
• People aged less than 18 or greater than 65
• People with an intellectual or mental impairment
• People in existing relationships with any member of the research team
• Women who are pregnant or breastfeeding
• People who are highly dependent on medical care (taking more than 5 regular medications)
• People taking regular anticoagulant medications other than low dose aspirin, or have a contraindication to anticoagulant medications

5. ‘How is this study being paid for?’
The study is being sponsored by Marinova Pty Ltd, the manufacturers of Maritech® Synergy.

All of the money being paid by the sponsor to run the trial will be deposited into an account managed by School of Pharmacy, UTAS. No money is paid directly to individual researchers.

6. ‘Are there risks to me in taking part in this study?’
All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are:
• Minor allergic reaction to Maritech® Synergy, which might involve rash or hives.
• Possibility of pain and bruising around the site where the blood is withdrawn.
• Possibility of hyperglycaemia as the study involves the consumption of a glucose drink, which could increase your blood sugar levels.

There may also be risks associated with this trial that are presently unknown or unforeseeable.

While likely to be safe, the effects of Maritech® Synergy on an unborn baby are unknown. If you are a woman of childbearing age you will only be allowed to participate if using highly reliable contraception (such as oral or implanted contraception, an IUD or have had a tubal ligation).

7. ‘What happens if I suffer injury or complications as a result of the study?’
If you suffer any injuries or complications as a result of this study, you should contact Cameron Wright, as soon as possible, who will assist you in arranging appropriate medical treatment.
You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

The parties to this study agree to follow the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial. These Guidelines allow for some claims for compensation to be settled without the need for legal action to be taken. You can obtain a copy of these Guidelines from the Executive Officer of the Tasmanian Health and Medical Human Research Ethics Committee.

8. ‘Will I benefit from the study?’
This study aims to further medical knowledge and may improve future treatment of diabetes; however it will not directly benefit you.

9. ‘Will taking part in this study cost me anything, and will I be paid?
Participation in this study will not cost you anything. You will be reimbursed for your time and reasonable travel expenses to the amount of $400 (gift card) at the completion of the 3 month trial.

10. ‘How will my confidentiality be protected?’
Of the people treating you, only the researchers named above will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above will have access to your details and results that will be held securely at School of Pharmacy UTAS.

11. ‘What happens with the results?’
If you give us your permission by signing the consent document, we plan to
present the results at conferences or other professional forums, publish the results in peer-reviewed journals and disclose the results to the sponsor for monitoring purposes and the HREC for monitoring purposes.

In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

12. ‘What happens to my treatment when the study is finished?’
This study involves you taking a 500 mg dose of the study drug or placebo twice daily for 3 months. If you choose to take Maritech Synergy® after the completion of the study, it is commercially available and you may continue to do so at your own expense. We strongly recommend that you discuss this decision with your general practitioner if you wish to take Maritech Synergy®.

13. ‘What should I do if I want to discuss this study further before I decide?’
When you have read this information, the researcher Cameron Wright, will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact her on 03 6226 1096.

14. ‘Who should I contact if I have concerns about the conduct of this study?’
This study has been approved by the Tasmanian Health and Medical Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study should contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 7479 or email human.ethics@utas.edu.au. The Executive Officer is the person nominated to receive complaints from research participants. You will need to quote HOO13608.

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.