جامعة محمد بن راشد
للطب و العلوم الصحية

MOHAMMED BIN RASHID UNIVERSITY
OF MEDICINE AND HEALTH SCIENCES

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INFORMED CONSENT FORM

Informed Consent Form

Investigating the anti-inflammatory effects of Frondanol in adults with inflammatory bowel disease

Informed Consent to Participate in a Research Study

This study has been approved by the MBRU-Human Research Ethics Committee [HREC Approval # .....]

Principal Investigator: Dr. Reem Jan

Co-investigators: Prof. Thomas Adrian, Dr. Jamil Akhras, Prof. Samuel Ho, Dr. Aida Azar, Dr. Fahad Ali, Dr. Hardik Ghelani, Dr. Mazin Aljabiri, Dr. Usama Warshow, Dr. Hossam Al-Hilou

Address: Mohammad Bin Rashid University of Medicine and Health Sciences
Building No 14, Dubai Health Care City
Dubai - UAE

Phone: 800- MBRU (6278) ext. 8733, 8745 or 8749

Site where the study will be conducted: Mediclinic Middle East Hospitals, Dubai, UAE and Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, UAE

You are invited to participate in this research study conducted at the Mohammad Bin Rashid University of Medicine and Health Sciences (MBRU) and Mediclinic Middle East Hospitals. Please, take your time to read the following information carefully, before you decide whether you wish to take part in this research study or not. You are encouraged to ask the study investigator if you need any additional information or clarification about what is stated in this form and/or in the research study as a whole. You are also free to take this information sheet and consult with your doctor or other health professionals. Please note that, should you decide to participate, you are free to withdraw at any time without any consequence.

Should you have any concerns whatsoever about the research, not adequately addressed by the principal investigator or co-investigators, you can contact the MBRU human research ethics committee (HREC) office directly at irb@mbru.ac.ae or +971 4 383 8706 and your request will be answered by someone not connected to the research. If you agree to be research participant, these contacts are also available if you are not satisfied by the manner in which the research is being conducted.

I. Purpose of the Research Study and Overview of Participation

Dr. Reem Jan and colleagues are conducting a research study to investigate the anti-inflammatory properties of a widely available nutraceutical extract of the edible sea cucumber, named Frondanol, in inflammatory bowel disease. Frondanol has been shown to markedly decrease inflammation in a mouse model of inflammatory bowel disease, as well as several other inflammatory disorders. In order to this, we need to compare inflammatory markers in the blood and in biopsy samples (obtained during your routine colonoscopy) between patients who take Frondanol and others who take inactive capsules (placebo) daily for six months. If you agree to take part in the study, you will be randomly assigned to take either Frondanol or placebo daily for six months, along with your usual standard medications. Your blood and tissue biopsies will be obtained at the start of the study and at the end of the six-month period. For this study we would like to ask you to donate a small sample of blood (10 ml) that would be taken at the same time as other blood tests you need for your routine care. During your routine care colonoscopies, your consultant gastroenterologist typically acquires 10-15 biopsies for the purposes of monitoring your disease. We would like to ask for your consent to allow for an additional 2-4 biopsies to be acquired so that we can study the effects of Frondanol on colon tissue inflammation, both at the start of treatment and six months later. There will be approximately up to 100 participants in this study. In the future the knowledge gained may help develop new treatments for patients with inflammatory bowel disease.

If you agree to be in the study, the following will happen to you:

1. You will continue to receive your current treatment for inflammatory bowel disease

2. You will be asked to consent to the study by reading and understanding this form and discussing it with the study coordinator, the principal investigator or your consultant gastroenterologist or nurse
3. If you agree, you will be randomly assigned to receive Frondanol or placebo daily, and to take it for the duration of six months, unless you decide to withdraw from the study, or have an untoward event. You and the study team will be blinded to which of the two treatments you will be receiving. Only one member of the study team will know what you are receiving (unblinded). Your name will not be used on study records, instead your identity will be assigned a code by the unblinded study team member and the code will be used henceforth (for data storage and analysis).
4. If you agree, you will be asked to donate a small sample of blood (10 ml) that would be taken at the same time as other blood tests you need for your routine care, at the start of the study, at three months, and at six months (end of study)
5. If you agree, an additional 2-4 biopsies will be collected during your routine colonoscopy procedures, both at the start of the study and six months later
6. All blood and tissue samples will be stored and studied at a later date. Samples will also be stored for future research that may be related to substances that cause inflammation in the body. You will not be informed of the results of specific experiments, but the overall results will be reported in aggregate at the end of the study and you may have access to these final results after they are presented to the scientific community.
7. In addition, we will record details related to your current condition such as your vital signs, age, gender, medical history, and other current blood test results.

Specimens:

The samples collected as a part of this research project will be given a code number only and no other identifying information. The principal investigator will keep the identity of the samples confidential and stored on a protected computer server at MBRU. The anonymous samples will be analyzed by the research team at MBRU to investigate the anti-inflammatory properties of Frondanol in comparison to placebo.

The specimens may also be used for future research. If you prefer, you may limit the future research to:

a. No limitation
b. with limitations including: (check one or more)
    i. Only research by the principal investigator or other researchers
    ii. Only research related to inflammatory bowel disease

Research results or reuse of the specimen will not be conveyed to you, and you will not be re-contacted after the original study is completed. In the future, if you request, the remaining specimens and all links to the clinical data be destroyed, we will honor that request.

II. Any Risks as a Result of Participating in the Study

Participation in this study may involve some added discomforts. The procedures used may cause:

a. Frondanol intake – there have been more than 3 million capsules of Frondanol consumed on the human market over the past 25 years with no reported side effects

b. Blood draw – may involve slight bruising at the site of blood draw

c. Biopsy acquisition – colonoscopy with biopsy is routine care for patients with colitis. The risk of serious harm such as causing bleeding or perforation (hole in the colon) from a colonoscopy is about 2-3 cases per 1000 colonoscopy procedures. The increased risk of taking additional biopsies, for the purposes of this research, after all routine biopsies are taken is considered to be very small.

Since this is an investigational study there may be some unknown risks that are currently unforeseeable. You will be informed if the researchers learn of any change in the amount of risk to you.

III. Any Benefits as a Result of Participating in the Study

There may be some direct benefits from participation in this study, if Frondanol is found to decrease gut inflammation in human inflammatory bowel disease patients. In the future, the knowledge gained from this study may help develop new natural treatments for patients with inflammatory bowel disease.

IV. Any Alternative Treatment

You will continue to receive your standard therapy. If you do not participate in the study, there is no consequence to you or the care you receive.

Voluntary Participation

Your participation in the study is entirely voluntary and you may refuse to participate or discontinue participation at any time without penalty or loss of benefits to which you would normally be entitled. Your decision about whether or not to participate in the study will not affect your relationship with MBRU or medical treatment at the hospital/clinic, if applicable.

Withdrawal from Study

You are at liberty to withdraw from the research study at any stage, without prejudice. Should any new information become available that may affect your willingness in participation, you will be informed in a timely manner. However, the principal investigator or designee may take you out of the study at any time with or without your agreement. This may happen for example if it is in your best medical interest to stop your participation, or if the study is canceled. If you wish to withdraw from the study, any collected data will be safely stored for ten years following the completion of the study then discarded in a confidential manner that does not risk identifying your personal information.

Costs/Payments

There are no costs to you for participating in this study.

Research-related adverse event(s)

In the event of illness or physical injury resulting from being a research subject in this study, you should immediately inform the principal investigator at: reem.jan@mbru.ac.ae or +971 4 383 8733, as well as the human research ethics committee (HREC) at irb@mbru.ac.ae or +971 4 383 8706. You will be instructed on the next steps by the principal investigator who will perform a causality assessment to ascertain whether the adverse event was related to participation in the trial. If the adverse event is deemed to be related to participation in the trial, you will be advised to immediately stop taking the study medication (whether Frondanol or placebo) and will be provided with the necessary medical care until the issue is resolved.

Confidentiality of data

If you agree to take part in this research study, please be ensured that the obtained information will be kept confidential. Unless required by law, only the study investigator or designee, the MBRU human research ethics committee (HREC), and/or inspectors from governmental agencies will have direct access to your information.

All research results would be anonymized with no individual identifying information. Data would be stored in a secured manner either electronically (password-protected spreadsheets) or manually (in a locked cabinet).

Dissemination of data

The principle of research is to obtain data and results to benefit society and, in this context, research may be published. Due to the anonymizing nature of data collection, you will not be

personally identified in any publication. Research data may be kept indefinitely as use of such data is sometimes required by other researchers and occasionally by editors of publications.

Investigator's Statement:

I have reviewed, in detail, the informed consent document for this research study with _____ _____ (name of patient, legal representative, or parent/guardian) the purpose of the study and its risks and benefits. I have answered to all the participant's questions clearly. I will inform the participant in case of any changes to the research study.

_____	_____	_____
Name of Investigator or Designee	**Signature**	**Date & Time**

Patient's Participation:

I have read and understood all aspects of the research study and all my questions have been answered. I voluntarily agree to be a part of this research study and I know that I can contact Reem Jan at 04 383 8733 or any of her team involved in the study in case I have any questions. If I feel that my questions have not been answered, I can contact the MBRU-HREC. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will not affect my care or benefits. I know that I will receive a copy of this signed informed consent.

_____	_____	_____
Name of Patient/Legal Representative or Parent/Guardian	**Signature**	**Date & Time**

_____	_____
Name of the Witness (if patient, representative or parent do not read)	**Witness's Signature**
	_____
	Date & Time

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Version Control Table

Version	Date	Author	Rationale
1.0	14/03/21	Reem Jan	First consent form version submitted to MOHAP
2.0	24/08/21	Reem Jan	Second version with updated 'research-related adverse event(s)' section as requested by MOHAP following initial review – approved 01/09/21
2.1	19/10/21	Reem Jan	Version 2.1 includes the addition of post-doctoral fellow Dr Hardik Ghelani to the list of investigators
2.2	30/11/21	Reem Jan	Addition of coinvestigator Dr Mazin Aljabiri to the list of investigators
2.3	04/12/21	Reem Jan	Addition of coinvestigators Dr Usama Warshow and Dr Hossam Al-Hilou