



INFORMATION FOR PARTICIPANTS

D-Lactic acid and D-lactic acid producing bacteria in patients with chronic fatigue syndrome

Please read the following information carefully and take home with you for future reference.

If you wish to participate in this study please make an appointment to see

Dr Ian Buttfield as soon as possible to commence arrangements.

Purpose of the Study

This is a research project. The purpose of this study is to identify changes in CFS patients by measuring levels of specific chemicals in urine, blood and faecas in a clearly defined group of sufferers. The specific chemicals are "organic acids", especially lactic acid. A further aim of this study is to see if the changes in these organic acids can be related to changes in the bacteria in the gut. Studying and comparing these changes in patients against those from individuals with little or no symptoms may further help to understand the disease.

The ultimate aim is to understand these changes so that they can be corrected with specific treatments which will help improve symptoms for patients.

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It must be understood that agreement or refusal to participate in this study will not affect your medical care. The study is under the direction of Dr Ian Buttfield (Adelaide), Dr Henry Butt (Melbourne), and A/Prof. Paul Gooley (Melbourne).

Description of Study

If you wish to participate in the study it is necessary for you to undergo a medical examination. A urine, blood and a faecal sample will be collected for analysis during the course of the study. The suitability of you as part of the study will depend both on the medical examination and laboratory results.

If you consent to participate in this study you will be asked to attend Dr Buttfield's clinic (90 Unley Rd, Unley, SA, 5061) for a medical examination. If you are accepted in the study by Dr. Buttfield you will need to provide a urine, faecal and blood sample and to complete and return a 86-questionnaire at a date suitable to you and Dr. Buttfield. Dr. Buttfield will be responsible for collecting your blood sample on that date. The questionnaire can be completed, and the urine and faecal sample to be collected the day before your appointment for the blood test

There should be no recognized risk in taking part in the study.

General Points

The data from this study will be reviewed by the investigators and by the staff of Bio 21, Molecular Science and Biotechnology Institute, University of Melbourne. Data obtained from the investigation will also form part of a study of a post-graduate student (Mr. Chris Armstrong) and may be published in medical journals and presented at International Meetings. In such cases your name will not be included and confidentiality will be maintained.

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All medical examinations, and laboratory tests are cost free to you. Results from the urine, faecal and blood tests will be made available to you after the study.

Please read the consent form carefully. Having signed the consent form you do not have to participate in the study and may withdraw at any time. The investigators reserve the right to withdraw you from the study at any time. If you have any questions concerning the study please do not hesitate to ask.

The University requires that all participants are informed that if they have any complaints concerning the manner in which a research project is conducted, they may be given to the researcher, or if an independent person is preferred, to the Executive Officer, Human Research Ethics, The University of Melbourne, ph: 8344 2073; fax 9347 6739

Telephone Contact of Investigators:

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Dr. Neil McGregor (MDS, PhD)	(03) 9509-6939
Dr. Henry Butt (MSc, PhD)	(03) 9349-5933

Yours Sincerely

Henry Butt Senior Fellow (Hon) Bio 21 Molecular Science & Biotechnology Institute University of Melbourne

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