CHRISTIAN MEDICAL COLLEGE, VELLORE

DEPARMENT OF GASTROENTEROLOGY AND WELLCOME RESEARCH LABORATORY

INFORMED CONSENT

Study title: "Clinical profile and epithelial barrier gene polymorphisms (PTPN2) in patients with Crohn's disease"

Research aim: To assess the frequency of PTPN2 gene polymorphisms in patients with Crohn's disease and matched controls.

Place of study: Gastroenterology and Wellcome research laboratory, Christian Medical College and Hospital, Vellore.

Name of Principal Investigator:

Dr. Kaushik Chatterjee, Senior PG registrar, Dept of Gastroenterology, CMC Vellore.

PART I: PATIENT INFORMATION

About the study

Introduction

Chronic diarrhea is a relatively common problem among patients presenting to Gastroenterology department. Crohn's disease is an important cause of diarrhea. It affects people in their young age and has relapsing and remitting course throughout the life. The reason behind this disease has been an enigma till date. It is thought that abnormal genetic makeup predisposes to this disease and in presence of appropriate environmental trigger the disease precipitates.

What is Crohn's disease?

Crohn's disease is an immune mediated disease. It can lead to persistent diarrhea, abdominal pain, weight loss, malabsorption and malignancy. The diseases need to be diagnosed and initiated on treatment early to prevent disease complications and severity.

Purpose

Purpose of this study is to check for the presence of PTPN2 genetic polymorphism in patients with Crohn's disease and controls. Thus to compare between these two groups and find any difference if

at all present. If there is any significant difference then we can think that the abnormality of PTPN2 gene may have contributed to Crohn's disease.

Participant selection

We will include patients presenting to the OPD or ward with Crohn's disease who are willing to participate in the study. Similarly non- ulcer dyspepsia patients who are willing to participate in the study will be included. Patients will be recruited till adequate sample size is reached.

Procedure

Blood sample will be collected by trained personnel.

Risks

It is unlikely that any risk is involved in participation in this study. The identity of the participant will be kept confidential.

Benefits

Your participation in the study will provide knowledge about the etiology of Crohn's disease.

Reimbursements

The participants of the study are expected to have no harmful effects because of their participation in the study and thereby we do not except any need for compensation.

Confidentiality

Your name will not be mentioned anywhere neither the data sheet nor the final published study. Your data will bear a study number and the number will be used till analysis.

Sharing of the results:

The output of the research can be published in a journal or presented in a conference for academic purposes.

Future studies:

Please note that the sample of blood collected will be stored and besides using for this study, with your consent will be used for future studies.

Right to refuse or withdraw

The participant has the right to refuse participation in the study and can withdraw when he/she wishes.

This proposal has been reviewed and approved by [IRB, Christian Medical College], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact

Research Office, second floor, Carman block, Christian Medical College, Bagayam, Vellore 632002.

Email:research@cmcvellore.ac.in telephone: 04162284294.

It has also been reviewed by the Ethics Review Committee CMC Vellore, which is supporting the study.

If there are any further queries regarding this study, you can contact me at

Dr Kaushik Chatterjee

Senior PG registrar

Dept of Gastroenterology and Hepatology

Christian Medical College, Vellore.

Mobile phone number: 9874299747

PART II: CERTIFICATE OF CONSENT

Subject's Initials: _____

Subject's Name: _____

Date of Birth / Age: _____

(Subject)

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.[ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that *the primary investigator, co-investigators and* the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

(v) I agree to take part in the above study. [ ]

(vi) **Optional – Participant can choose to opt in or opt out of this particular section of the consent form**

I understand that my blood and stool sample will be stored for future studies. I understand that my stored samples may be used in future for genetic studies, microbiota analysis, inflammatory/molecular markers. **[Opt in / Opt out]**

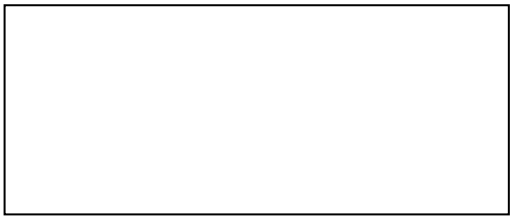
Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: _____/_____/_____

Signatory's Name: _____

Signature:

Or



Representative: _____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature (or) thumb impression of the Witness: _____

Date: _____/_____/_____

Name and Address of the Witness: _____

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