

Participant information sheet

Predicting 5-aminosalicylate induced nephrotoxicity in patients with inflammatory bowel disease.

You are being invited to take part in a research study. Before you decide, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

5-aminosalicylate drugs are frequently prescribed to treat patients with ulcerative colitis and Crohn's disease. For the majority of patients these drugs are effective at controlling symptoms, and side effects are rare and usually mild. Unfortunately a tiny minority of patients (like you) develop more serious side effects. These include kidney damage, a rare unpredictable side effect of treatment with 5-aminosalicylate drugs. At present we do not know why this happens.

Recent evidence suggests that side effects to some drugs may be determined by our genes (the basic building blocks of life). The purpose of this study is to identify the genes which determine kidney damage caused by 5-aminosalicylate drugs. It is hoped that we might then be able to develop a test to predict which patients will develop these serious side effect before patients are treated. We require your permission to include you in this study.

Why have I been asked to participate?

You have been asked to participate because we believe you have Crohn's disease or ulcerative colitis and have experienced kidney damage whilst taking a 5-aminosalicylate drug.

5-aminosalicylate drugs include Mesalazine (Asacol®, Pentasa®, Mesren®, Salofalk®, Mezavant®, Ipoocol®), Balsalazide (Colazide®), Olsalazine (Dipentum®), Sulphasalazine (Salazopyrin®)

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you would be given this information sheet to keep, and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

If you decide to take part we will ask your permission to look at your medical records, ask you to complete a short questionnaire, and ask you to provide us with a sample of your saliva (using the kit which we will provide) or blood sample (which we will arrange). We will provide a prepaid envelope to post these items back to us. We will extract DNA from your saliva or blood sample for genetic analyses. If after review of your medical notes it is felt that you do not meet the criteria for inclusion in the study we will write to you and destroy your DNA sample.

What are the possible benefits of taking part?

There are no direct benefits to you of taking part but it is hoped that information we get from this study may help us in the future to improve treatment for patients with ulcerative colitis and Crohn's disease.

Are there any risks to me?

You may experience some minor discomfort at the venepuncture site but otherwise there are no known risks from taking part in this study. Taking part in the study will not affect your current treatment, nor will it affect your ability to obtain insurance for health purposes.

What will happen to my DNA?

DNA will be extracted from your saliva or blood sample at the Peninsula Medical School. Your DNA sample will be given a code number so that your identity will not be revealed to laboratory staff or those performing the genetic analyses. Only the Chief Investigator will be able to link your coded DNA sample to you. All coded clinical details will be kept securely, at the Peninsula Medical School. Your coded DNA sample will be sent to other centres in the UK and USA for genetic analyses but your personal details will be removed and remain confidential.

Your saliva or blood sample will be considered a gift to the Peninsula Medical School, which will act as custodian of all samples obtained as part of this project. DNA may be stored indefinitely for future genetic studies in the UK and overseas aimed at understanding the genetic factors involved in Inflammatory Bowel Disease and its treatment. Genetic results may be used to identify specific patients for further studies and any future studies would require approval by an ethics committee.

If I participate will my personal medical information be kept confidential?

All information that is collected about you during the course of the project would be kept strictly confidential. All DNA samples received by the University will be identified by a code number only. Any information about you, which leaves the research centre, will have your name and address removed so that you cannot be recognised from it.

We will write to your GP to inform them of your participation in this study.

What would happen to the results of the research study?

We hope to be able to publish the results of this research and will be happy to provide you with a copy of the publication if you request it. You will not be identifiable in this publication.

Individual data will not be made available to participants unless the results could potentially impact on the individual's clinical care. Results would then be shared with the participant and their GP. This decision would be made by Dr Tariq Ahmad.

Will I be paid for taking part in the study?

We are unfortunately unable to pay people for taking part.

Who has reviewed the study?

The study has been reviewed by the South West 1 Research Ethics Committee 10/H0203/76.

Who is organising and funding the research?

This study is funded by the International serious adverse event consortium (SAEC) and supported by the National institute for health service research clinical research network (NIHR CRN) and the Peninsula Medical School.

I have some further questions, who can I ask?

If you would like any further details, or you would simply like to leave a message by telephone rather than writing, please contact:

Mrs Suzie Mariott	Research nurse	01392 XXXXXX
Dr Tariq Ahmad	Consultant Gastroenterologist	01392 406218