

Cambridge Crohn's and colitis gene study: *Can you help?*

Information for controls

In collaboration with the Cambridge BioResource we are inviting you to act as a 'healthy control' in a research study to investigate the genetic basis of ulcerative colitis and Crohn's disease. Before you decide it is important for you to understand why the research is being done. Please take time to read the following information carefully and discuss it with others if you wish. Phone us to ask if there is anything that is not clear or if you would like more information.

Thank you for reading this.

Ulcerative Colitis and Crohn's Disease

These are debilitating conditions affecting the intestine, and together are known as inflammatory bowel disease (IBD). Mainly affecting young adults, their cause is unknown. Nevertheless, it is now clear that several inherited factors (genes) are important in determining an individual's susceptibility to ulcerative colitis or Crohn's disease, and in determining the way that the diseases behave.

Current IBD therapies are far from ideal - having many side effects and often being ineffective. Thus major abdominal surgery is required in over 75% of patients with Crohn's disease due to loss of response to treatment. Many patients with IBD face the prospects of life with an ileostomy or colostomy. In this study we hope to further our understanding of which genes are involved in the development of IBD, to inform development of better treatments. Over the next three to five years we hope that the results of this research will be published, and will help to

- increase our understanding of the cause of these diseases.
- improve targeting of existing treatments.
- allow development of better therapies.

Why have I been chosen?

To identify the genes that are associated with inflammation in the bowel, we need to study DNA and RNA both from individuals with Crohn's or colitis and from people without these diseases ('controls'). An advantage in seeking controls from the Cambridge BioResource is that we can focus efforts on volunteers of known genetic make-up, particularly with regard to genetic variants known to be relevant to IBD. If you are willing to help as a control we would like to take a blood sample for this research.

Will the results of my genetic analysis remain confidential?

Your blood will be given a code number so that your identity will not be known to laboratory personnel. The research does not constitute a 'genetic test' as defined by insurance companies.

What do I have to do?

To help us with the research, we would ask you to:

- sign a form that gives your consent to take part in the study.
- donate a small volume (10-20 mls=2-4 teaspoons) of blood.
- The potential risks of giving a blood sample are very small: you might get a small bruise, and if you are prone to fainting do warn the person taking your blood.

What happens to my blood sample?

We extract the DNA and RNA (the substances that comprise the body's genetic code) from the blood sample and this is stored for later analysis. By analyzing variation in DNA / RNA and how this affects 'reading' of the genetic code (and thus its

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impact on cell function) in both affected individuals and healthy controls we aim to identify how and why genetic variants predispose to Crohn's and colitis.

Who is doing the research?

The research is based in the Gastroenterology dept at Addenbrooke's in Cambridge: the project is being led by Dr Miles Parkes who has a particular interest in this field, but many consultants and their teams in the Anglia region are helping. (*The study has the approval of the Cambridge LREC*). The researchers are not being paid to recruit individuals to this study.

What happens to the results of this study?

Results from the analysis of the group data in this study will be discussed at scientific meetings and published in scientific journals.

When is the research likely to benefit patients?

Identifying most of the genes that determine susceptibility to Crohn's and colitis is likely to take at least five years, although we may be able to define the genes that influence how the disease will behave rather more quickly. The results should provide new directions for the development of better treatment. We might expect new drugs to appear in 15-20 years.

Are there financial implications?

While the aim of this research is purely to advance our understanding of Crohn's and colitis, if it does result in findings which have a commercial application you would not be able to claim any financial payment (in legal terms the sample is a 'gift'). We will ensure that:-

- any discoveries or inventions are patented, both to maximise the value of

the research and to provide incentives for companies to develop the new drugs

- all revenues from any industrial involvement are channelled back into Crohn's and colitis research.

Can I choose not to take part?

Yes, of course. Participation is entirely voluntary and if you prefer not to be involved, you need not give a reason. If you decide to take part we will ask you to sign a consent form. You can still withdraw at any stage and your sample will be destroyed.

Who should I talk to if I have any questions or concerns?

Please feel free to contact Dr Miles Parkes, or Sister Fran Bredin, Department of Gastroenterology, Box 133, Addenbrooke's Hospital, Cambridge.CB2 2QQ.
Tel: 01223 586739

Thank you for taking part in this study!

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