

# Can we prevent Crohn's disease: a National study

<b>Submission date</b> 01/03/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/04/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/09/2012	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
G0500274

## Study information

**Scientific Title**  
Assessing and reducing risk of Crohn's disease in smokers

**Acronym**

GRAB

### **Study objectives**

Current hypothesis as of 28/04/2008:

The trial objective is to describe the impact upon motivation to stop smoking using genotype to assess risk of developing Crohn's disease (CD).

The primary hypothesis is that participants are more likely to make smoking cessation attempt following the communication of their risk of developing CD that incorporates genotype analysis in addition to family history and smoking status, compared with a communication of risk of CD that does not incorporate genotype analysis.

Previous hypothesis:

The trial objective is to describe the impact upon motivation to stop smoking using genotype to assess risk of developing Crohn's disease.

The primary hypothesis: a higher proportion of participants will engage in one or more quit-related behaviours over the six months since the intervention.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from the Hertfordshire Research Ethics Committee on the 26th June 2006 (ref: 06/Q0201/19). Most recent Substantial Amendment (5.0): 9th October 2007.

### **Study design**

Parallel group randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Crohn's disease

### **Interventions**

The trial objective is to describe the impact upon motivation to stop smoking of using genotype to assess risk of developing Crohn's disease. We will compare the impact of risk assessment based on family history and DNA testing versus assessment based on family history alone.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

Current primary outcome as of 28/04/2008:

Stopping smoking for 24 hours or longer in the six months following provision of risk information.

Previous primary outcome:

The proportion of participants in each group engaging in 1 or more quit-related behaviours, measured 6 months after participants are presented with their personalised risk information.

**Key secondary outcome(s)**

The proportion of participants in each group who make smoking quit attempts of 6 or more days duration. This will be validated using questionnaires and biochemical indices.

**Completion date**

31/12/2009

## **Eligibility**

**Key inclusion criteria**

1. First degree relatives of patients with Crohn's disease
2. Aged over 18 years
3. Living in the British Isles
4. Without a diagnosis of Crohn's disease or ulcerative colitis
5. Male or female
6. Smoke 5 or more cigarettes daily
7. Able to give informed consent to participate
8. Able to complete, either alone or with assistance, the study questionnaires

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Those not meeting the inclusion criteria

**Date of first enrolment**

01/01/2006

**Date of final enrolment**

31/12/2009

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

Health Psychology Section

London

United Kingdom

SE1 9RT

# Sponsor information

## Organisation

King's College London (UK)

## ROR

<https://ror.org/0220mzb33>

# Funder(s)

## Funder type

Research council

## Funder Name

Medical Research Council - Health Services and Public Health Research Board (HSPHRB; ref G0500274) (UK)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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<a href="#">Results article</a>	results	20/07/2012	Yes	No
<a href="#">Protocol article</a>	protocol	19/01/2011	Yes	No