

# 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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.

## **Secondary outcome measures**

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.

## **Overall study start date**

01/01/2006

## **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

## **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

500

**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**

England

United Kingdom

**Study participating centre****Health Psychology Section**

London

United Kingdom

SE1 9RT

**Sponsor information****Organisation**

King's College London (UK)

**Sponsor details**

Institute of Psychiatry

De Crespigny Park

London

England

United Kingdom

WC2R 2LS

**Sponsor type**

University/education

**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

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**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?
<a href="#">Protocol article</a>	protocol	19/01/2011		Yes	No
<a href="#">Results article</a>	results	20/07/2012		Yes	No