

Can we prevent Crohn's disease: a National study

Submission date 01/03/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 26/04/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/09/2012	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Theresa M Marteau

Contact details
Health Psychology Section
Department of Psychology (at Guy's)
5th Floor Thomas Guy House
Guy's Campus
London
United Kingdom
SE1 9RT

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.

Primary study design

Interventional

Study design

Parallel group randomised controlled trial

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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Results article	results	20/07/2012	Yes	No
Protocol article	protocol	19/01/2011	Yes	No