ISRCTN67248113 https://doi.org/10.1186/ISRCTN67248113

The PREdiCCt Study: the prognostic effect of environmental factors in Crohn's and colitis

Submission date
29/08/2016

Recruitment status
No longer recruiting

Registration date
11/05/2017

Overall study status
Completed

Last Edited
13/12/2022

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Inflammatory bowel disease (IBD) is a term used to describe conditions which cause long-term (chronic) inflammation (swelling) in the digestive tract (gut), and includes Crohn's Disease and Ulcerative Colitis. It can make sufferers quite weak lacking energy and enthusiasm, typically giving them abdominal pain, bloody diarrhoea and nausea. The symptoms can be extreme enough to affect all aspects of day-to-day living. This can mean that sufferers don't do so well at school or in the workplace, can be more socially isolated and as a result can suffer increasing levels of anxiety and depression. There is currently no cure for these conditions, and so the main aim of treatment is to reduce the symptoms (remission) and prevent the disease from "flaring up" and becoming active again. There are a range of treatments however many have toxic side effects which often outweigh the benefits. The response to the various treatments can be variable and sometimes what will work in one person won't work in others. In addition a drug can work for a period of time and then stop working. In some patients the side effects are such that they are unable to tolerate that particular treatment. All too often sufferers need major surgery - more than 50% with Crohn's disease and 15-30% with ulcerative colitis. In recent years, researchers have gained a better understanding of the underlying causes of IBD. For example, a person's genetic makeup is thought to play a role in why people get IBD, but cannot be used to predict if a patient's IBD will be mild or severe or what causes flare ups. It has also been found that the bacteria that live in the gut (microorganisms) are different in patients with IBD, but it is not known whether these different microorganisms cause IBD or are caused by IBD's gut inflammation. It is possible that environmental factors (infections, drugs, and dietary factors) play an important role, probably by altering the gut microorganisms, but this has not yet been proven. The aim of this study is to investigate how environmental factors and the gut microorganisms influence IBD flare and recovery.

Who can participate?
Patients with inflammatory bowel disease who are in remission and aged 6 years and over

What does the study involve?
Participants attend a clinic visit for routine tests and also to complete several questionnaires with a research nurse. At home over the next week participants will complete detailed questionnaires assessing their environment and diet. They will also collect a stool and saliva

sample and send this to our laboratories (we've developed easy ways of doing this reliably by post). The stool sample is to analyse the microorganisms in the participant's gut and the saliva is used to analyse their DNA. Participants are then followed up monthly over the next 24 months using short questionnaires completed online. They also complete a longer questionnaire after 12 months and 24 months. If a participant experiences a flare up, an additional stool sample is collected in order to how the environmental and microorganism factors recorded at the beginning differ for those that flare up versus those that don't.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
University of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
June 2016 to December 2022

Who is funding the study?
Chief Scientist Office (UK)

Who is the main contact?
Lisa Derr
lisa.derr@ed.ac.uk

Study website
http://www.predicct.co.uk/

Contact information

Type(s)
Public

Contact name
Ms Lisa Derr

Contact details
Edinburgh Clinical Trials Unit (ECTU)
Nine BioQuarter Room D.02.11
Little France Road
Edinburgh
United Kingdom
EH16 4UX
+44 (0)131 651 9918
lisa.derr@ed.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2

Study information

Scientific Title
The PRognostic effect of Environmental factors in Crohn's and Colitis

Acronym
PREdiCCt

Study objectives
The aim of this study is to establish which environmental and microbial factors are associated with disease flare.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee – The Black Country, 22/03/2016, ref: 16/WM/0152

Study design
Observational longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
http://www.predicct.co.uk/uploads/4/6/6/0/4660963/information_leaflet_v1_11.02.16.pdf

Health condition(s) or problem(s) studied
Inflammatory bowel disease

Interventions
Patients will be approached at routine clinic visits to invite them to participate in PREdiCCt. Following written informed consent, the clinical team will be asked provide information relating to the patients current disease status, demographic, phenotyping and medical information which will include taking blood for routine testing. No further visits to clinic for PREdiCCt are required.

Within the first week of recruitment into PREdiCCt patients will also be asked to provide a saliva sample (for genomic DNA) and a stool sample (for bacterial DNA, SCFA and faecal calprotectin) along with completion of a baseline questionnaire to collect information relating to their environment, lifestyle, and habitual diet via a custom designed web portal from home.

All patients are followed for a minimum of 24 months during which, on a monthly basis, they are asked to complete a short questionnaire relating to their symptoms, environment and lifestyle through the web portal. If a patient experiences a flare in their condition they will be asked to provide another stool sample and will continue to be followed up. Multiple endpoints can be reached by an individual during the course of follow-up however only the first endpoint reached will be used in the primary analysis. At the end of the 24 month follow up period a final questionnaire will be requested.

Intervention Type
Other

Primary outcome measure
Evidence of clinical flare determined by the patient answering “no” to the following question “Do you think your disease has been well controlled in the past 1 month?” at baseline and then monthly for 24 months.

Secondary outcome measures
Medication status will be reported by the patient directly (via a secure web portal) on a monthly basis for 24 months. Patients will be asked to record any changes to their drug regimen including dose alteration, addition of new medication, stop of medication.

Overall study start date
01/06/2016

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Confirmed Crohn’s disease or ulcerative colitis or IBDU (Lennard-Jones/Porto criteria) 59-60.
2. Clinical remission
3. More than 6 months since diagnosis with Crohn’s disease, ulcerative colitis or IBDU
4. More than 2 months since any change in therapy for Crohn’s disease, ulcerative colitis or IBDU
5. Aged six years or over at study entry
6. Written informed consent obtained from patient or parent/guardian

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
3100

Key exclusion criteria
1. Patient unwilling to take part in all aspects of the study
2. Unable to obtain written informed consent
3. Systemic corticosteroids (oral or intravenous) within the last two months
4. Thiopurines / methotrexate / biologic therapy started in the preceding two months

Date of first enrolment
30/09/2016

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
United Kingdom
G12 0XH

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
NHS Tayside
Kings Croos
Clepington Road
Dundee
United Kingdom
DD3 8EA

Study participating centre
NHS Highland
Reay House
17 Old Edinburgh Road
Inverness
United Kingdom
IV2 3HG

Study participating centre
NHS Lanarkshire
14 Beckford Street
Hamilton
United Kingdom
ML3 0TA

Study participating centre
Ulster Hospital
Upper Newtownards Rd
Dundonald
Belfast
United Kingdom
BT16 1RH

Study participating centre

Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Royal London Hospital and Associated Community Services NHS Trust
The Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
NHS Fife
Hayfield House
Hayfield Road
Kirkcaldy
United Kingdom
KY2 5AH

Study participating centre

Sandwell and West Birmingham Hospitals NHS Trust
City Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH

Study participating centre
NHS Forth Valley
33 Spittal Street
Stirling
United Kingdom
FK8 1DX

Study participating centre
The Queen Elizabeth Hospital
Gayton Road
King's Lynn
United Kingdom
PE30 4ET

Study participating centre
Buckinghamshire Healthcare NHS Trust
Amersham Hospital
Whielden Street
Amersham
United Kingdom
HP7 0JD

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Pinderfields Hospitals NHS Trust
Trust Hq, Rowan House
Pinderfields General Hospital
Aberford Road

Wakefield
United Kingdom
WF1 4EE

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Kingston Hospital
Galsworthy Road
Kingston upon Thames
United Kingdom
KT2 7QB

Study participating centre
Gateshead Hospitals NHS Trust
Queen Elizabeth Hospital
Sherriff Hill
Gateshead
United Kingdom
NE9 6SX

Study participating centre
Royal Hampshire County Hospital
Romsey Road
Winchester
United Kingdom
SO22 5DG

Study participating centre
Kings College Hospital
Mapother House
De Crespigny Park
Denmark Hill

London
United Kingdom
SE5 8AB

Study participating centre
Bronglais General Hospital
Bronglais Hospital
Caradoc Road
Aberystwyth
United Kingdom
SY23 1ER

Study participating centre
University Hospital Bristol
Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW

Study participating centre
Withybush General Hospital
Fishguard Road
Haverfordwest
United Kingdom
SA61 2PZ

Study participating centre
Salford Royal Hospital
Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

Study participating centre
West Suffolk NHS Foundation Trust
West Suffolk Hospital
Hardwick Lane

Bury St. Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Eastbourne Hospitals NHS Trust
Eastbourne District Gen Hospital
Kings Drive
Eastbourne
United Kingdom
BN21 2UD

Study participating centre
Darlington Memorial Hospital Cdc
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre
Guy's and St Thomas' Hospitals
Trust Offices
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Warrington and Halton Teaching Hospitals NHS Foundation Trust
Warrington Hospital
Lovely Lane

Warrington
United Kingdom
WA5 1QG

Study participating centre
Royal Berkshire Hospital
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
Kettering General Hospital NHS Foundation Trust
Rothwell Road
Kettering
United Kingdom
NN16 8UZ

Study participating centre
Royal Liverpool and Broadgreen University Hospitals NHS Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
West Wales General Hospital
Dolgwili Road
Carmarthen
United Kingdom
SA31 2AF

Study participating centre
The Royal Victoria Infirmary and Associated Hospitals NHS Trust
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
North West London Hospitals NHS Trust
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
James Paget University Hospital
Lowestoft Road
Gorleston
Great Yarmouth
United Kingdom
NR31 6LA

Study participating centre
St George's University Hospitals NHS Foundation Trust
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre

Maidstone
Maidstone Hospital
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre
Mersey Care NHS Trust at Aintree Hospital
C/o University Hospital Aintree
Fazakerley Hospital
Lower Lane
Liverpool
United Kingdom
L9 7AL

Sponsor information

Organisation
ACCORD

Sponsor details
Research Governance & QA Office
University of Edinburgh
The Queen's Medical Research Institute
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16

Sponsor type
University/education

Website
accord.scot

ROR
https://ror.org/01x6s1m65

Funder(s)

Funder type

Government

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/03/2023

Individual participant data (IPD) sharing plan
Data will be held at https://datashare.is.ed.ac.uk/ and applications to access data will be reviewed on an individual basis.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No