ISRCTN11043249 https://doi.org/10.1186/ISRCTN11043249

A study to assess the relationship between disease flare states and participant-reported health data, health data from a wearable activity tracker, and biomarker data in participants with inflammatory bowel disease (IBD)

Submission date 09/03/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol
Registration date 11/03/2022	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 04/12/2023	**Condition category** Digestive System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Inflammatory bowel disease (IBD) is a group of disorders that cause chronic inflammation (pain and swelling) in the intestines. The cause of IBD remains unknown, although hereditary and environmental factors may trigger inflammation. IBD includes two related diseases, ulcerative colitis (UC) and Crohn's Disease (CD). Both cause chronic or long-term inflammation in the digestive tract (gastrointestinal tract; GI) which are characterized by diarrhoea, rectal bleeding, abdominal pain, fatigue (tired, feeling of weakness) and unintended weight loss.

The participants living with IBD experience flares (an increase or worsening of IBD symptoms), which are unpredictable reappearances of intestinal inflammation and associated symptoms. IBD flares may lead to invasive procedures such as a colonoscopy and often require an escalation in medical management. Implementing a proactive approach to monitoring IBD flares remains a challenge. This is an observational study wherein researchers observe participants, and no study medications or treatments are given.

The main purpose of this study is:
To find out whether data collected from a Fitbit® activity tracker, surveys, and blood, stool, and saliva samples can be used to better understand and manage IBD.
To improve early detection and monitoring of IBD flares which could allow for earlier treatment and decrease the need for more invasive procedures such as a colonoscopy.
To find out whether data collected from a Fitbit® activity tracker, surveys, and blood, stool, and saliva samples can be used to predict IBD flares.
To assess the feasibility of collecting blood, stool, and saliva samples, PRO data, and activity tracker data via a decentralized process and to assess the quality of the resulting data

Who can participate?
People aged 18 years and above with Crohn's disease or Ulcerative Colitis.

What does the study involve?
Participants may be asked to be in the study for approximately 13 months. This includes:
Screening and Enrollment Period of up to 1 month where the participants will be checked for their eligibility by completing an online Screening Survey. Eligible participants will be provided with an activity tracker for data collection and asked to carry out a few tests at home. First, a mobile phlebotomist visit (home visit by personnel trained to collect blood and other biological samples) will be scheduled. Participants will also be asked to download the IBDoc CalApp to perform the first IBDoc at-home stool test.
Observation Period of approximately 12 months where participants will have to complete daily, weekly, bi-weekly surveys from the mobile app. They will be required to wear the activity tracker 24 hours a day and will have to perform a few at-home tests.

Participants will be placed in one of the following groups:
Group 1: Participants with UC will be observed for approximately 12 months.
Group 2: Participants with CD will be observed for approximately 12 months.

What are the possible benefits and risks of participating?
The participants will be paid based on the activities they perform in five payments, one payment upon enrolment and one payment every 3 months for the duration of the study. Apart from this, the information that is learned may help people with IBD in the future.
The study does not involve the testing of any new or experimental drugs or devices. Few potential risks are listed below:
Drawing blood can cause pain, bruising, or infection where the needle is inserted
Participants may experience dizziness, fainting, or upset stomach when the blood is drawn
Participants may experience skin irritation or discomfort on the wrist from wearing the Fitbit.
The lifestyle may be affected by having to wear a Fitbit all the time, including during sleep.
The sample collection kits could get lost in the mail and there is some risk to privacy due to the participant's name being present on the package
A minor risk is that people other than the study team could obtain and misuse genetic data from the blood sample
Genentech and Genentech's representatives (people and companies such as Evidation who work for Genentech) will not pay for any medical care for injury or illness related to the participation in this study.

Where is the study run from?
F. Hoffmann-La Roche (USA)

When is the study starting and how long is it expected to run for?
October 2021 to January 2024

Who is funding the study?
F. Hoffmann-La Roche (USA)

Who is the main contact?
Dr Jennifer Damman, global-roche-genentech-trials@gene.com

Study website

https://forpatients.roche.com/en/trials/autoimmune-disorder/ibd/an-observational-study-to-assess-the-relationship-between-diseas.html

Contact information

Type(s)
Public

Contact name
Dr Jennifer Damman

Contact details
1 DNA Way
South San Francisco
United States of America
94080
+1 888-662-6728
global-roche-genentech-trials@gene.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
XA43467

Study information

Scientific Title
An observational study to assess the relationship between disease flare states and patient-reported health data, health data from a wearable activity tracker, and biomarker data obtained through a decentralized process in patients with inflammatory bowel disease

Study objectives
IBD flares may be associated with changes in biomarker data generated from biological samples and participant health data as assessed through patient-reported outcome (PRO) measures and a wearable activity tracker.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approval pending, Western Copernicus Group Institutional Review Board (1019 39th Avenue SE, Suite 120 , Puyallup, WA 98374-2115, USA; +1 (800) 562-4789; Help@wirb.com), ref: IRB Pr #: 20220999, IRB Study #: 1328897

Study design
Phase 4 prospective exploratory cohort-based observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Inflammatory Bowel Disease (IBD)

Interventions
Cohort 1: Participants with ulcerative colitis (UC) will be asked to provide biological samples such as blood, stool, and saliva samples at regular intervals, complete daily, weekly, and bi-weekly surveys, and wear a study-provided Fitbit® activity tracker 24 hours a day for approximately 12 months.
Cohort 2: Participants with Crohn's disease (CD) will be asked to provide biological samples such as blood, stool, and saliva samples at regular intervals, complete daily, weekly, and bi-weekly surveys, and wear a study-provided Fitbit® activity tracker 24 hours a day for approximately 12 months.

Intervention Type
Other

Primary outcome measure
1. Distributional Differences in Biomarker Data Collected During IBD Flare State Versus Non-Flare State Measured Using Biological Samples over 52 Weeks
2. Distributional Differences in PRO Data Collected During IBD Flare State Versus Non-Flare State Measured Using Daily, Weekly, and Bi-Weekly Surveys over 52 Weeks
3. Distributional Differences in Activity Tracker Data Collected During IBD Flare State Versus Non-Flare State Measured Using Wearable Activity Tracker over 52 weeks
4. Within-Participant Changes in Biomarker Data Collected During IBD Flare State Relative to Non-Flare State Measured Using Biological Samples over 52 Weeks
5. Within-Participant Changes in PRO Data Collected During IBD Flare State Relative to Non-Flare State Measured Using Daily, Weekly, and Bi-Weekly Surveys over 52 Weeks
6. Within-Participant Changes in Activity Tracker Data Collected During IBD Flare State Relative

to Non-Flare State Measured Using Wearable Activity Tracker over 52 Weeks
7. Within-Participant Variability Versus Between-Participant Variability in Biomarker Data Measured Using Biological Samples over 52 Weeks
8. Within-Participant Variability Versus Between-Participant Variability in PRO Data Measured Using Daily, Weekly, and Bi-Weekly Surveys over 52 Weeks
9. Within-Participant Variability Versus Between-Participant Variability in Activity Tracker Data Measured Using Wearable Activity Tracker over 52 Weeks
10. IBD Flare Detection Performance, Utility, and Feasibility for Biomarker Data Compared with Benchmark Flare Detectors Measured Using Biological Samples over 52 Weeks
11. IBD Flare Detection Performance, Utility, and Feasibility for PRO Data Compared with Benchmark Flare Detectors Measured Using Daily, Weekly, and Bi-Weekly Surveys over 52 Weeks
12. IBD Flare Detection Performance, Utility, and Feasibility for Activity Tracker Data Compared with Benchmark Flare Detectors Measured Using Wearable Activity Tracker over 52 Weeks

Secondary outcome measures

1. Longitudinal Trends in Biomarker Data Collected During the Time Leading up to IBD Flare Measured Using Biological Samples over 52 Weeks
2. Longitudinal Trends in PRO Data Collected During the Time Leading up to IBD Flare Measured Using Daily, Weekly, and Bi-Weekly Surveys over 52 Weeks
3. Longitudinal Trends in Activity Tracker Data Collected During the Time Leading up to IBD Flare Measured Using Wearable Activity Tracker over 52 Weeks
4. Within-Participant Variability in Biomarker Data During Non-IBD Flare State Measured Using Biological Samples over 52 Weeks
5. Within- Participant Variability in PRO Data During Non-IBD Flare State Measured Using Daily, Weekly, and Bi-Weekly Surveys over 52 Weeks
6. Within- Participant Variability in Activity Tracker Data During Non-IBD Flare State Measured Using Wearable Activity Tracker over 52 Weeks
7. IBD Flare Prediction Performance, Utility, and Feasibility for Biomarker Data Compared with Benchmark IBD Flare Predictors Measured Using Biological Samples over 52 Weeks
8. IBD Flare Prediction Performance, Utility, and Feasibility for PRO Data Compared with Benchmark IBD Flare Predictors Measured Using Daily, Weekly, and Bi-Weekly Surveys over 52 Weeks
9. IBD Flare Prediction Performance, Utility, and Feasibility for Activity Tracker Data Compared with Benchmark IBD Flare Predictors Measured Using Wearable Activity Tracker over 52 Weeks
10. Percentage of Days or Weeks with Completed Surveys Using IBDoc CalApp over 52 Weeks
11. Percentage of Days with Complete Activity Tracker Data Using Wearable Activity Tracker over 52 Weeks
12. Percentage of Scheduled Mobile Phlebotomist Visits that are Completed over 52 Weeks
13. Percentage of Scheduled IBDoc® At-Home Stool Calprotectin Tests that are Completed over 52 Weeks
14. Adherence to Survey Completion Using IBDoc CalApp over 52 Weeks
15. Adherence To Mobile Phlebotomist Visits over 52 Weeks
16. Adherence To IBDoc At-Home Stool Calprotectin Tests over 52 Weeks
17. Agreement Between IBDoc At-Home and Sponsor Laboratory Stool Calprotectin Test Results over 52 Weeks
18. Within-Participant and Between-Participant Variability in Biomarker Distributions and Number of Biomarkers Detected Measured Using Biological Samples over 52 Weeks
19. Difficulty in Completing Study Activities as Reported by Participants on the Final Survey at Week 52

Overall study start date

01/10/2021

Completion date
31/01/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 01/08/2022:
1. Age of more than 18 years
2. Diagnosis of moderate-severe CD or UC by a healthcare provider via colonoscopy
3. One or more IBD flares in the previous 12 months, with a flare defined as an occurrence in an unplanned visit to a primary gastroenterologist or IBD specialist or the initiation of treatment to manage IBD or due to change in the medical management of IBD by a healthcare provider
4. The participant is a resident of the United States and can speak, read, and understand English
5. Agree to wear an activity tracker on the same wrist 24 hours a day (except when charging the tracker) for the duration of the study
6. Agreement to self-collect saliva and stool samples and store one stool sample in the freezer until pick-up at least every 4 weeks
7. Must have a smartphone that is compatible with the IBDoc CalApp (list of compatible devices is available at: https://www.ibdoc.net/support/?lang=en) and must be able to take an at-home stool test and upload results using a smartphone app every 2 weeks
8. Agreement and ability to store up to four sample kits in the refrigerator during the study
9. Agreement and ability to receive shipments at a mailing address that is not a post office box
10. Agreement and ability to have a mobile phlebotomist collect blood, stool, and saliva samples at home or at a place of their choosing at least every 4 weeks during phlebotomist business hours
11. Agreement to complete daily and weekly questionnaires

———

Previous inclusion criteria:
1. Age of more than 18 years
2. Diagnosis of moderate-severe CD or UC by a healthcare provider via colonoscopy
3. Two or more IBD flares in the previous 24 months, with a flare defined as an occurrence in an unplanned visit to a primary gastroenterologist or IBD specialist or the initiation of treatment to manage IBD or due to change in the medical management of IBD by a healthcare provider
4. The participant is a resident of the United States and can speak, read, and understand English
5. Agree to wear an activity tracker on the same wrist 24 hours a day (except when charging the tracker) for the duration of the study
6. Agreement to self-collect saliva and stool samples and store one stool sample in the freezer until pick-up at least every 4 weeks
7. Agreement to donate a blood sample for genome testing
8. Must have a smartphone that is compatible with the IBDoc CalApp (list of compatible devices is available at: https://www.ibdoc.net/support/?lang=en) and must be able to take an at-home stool test and upload results using a smartphone app every 2 weeks
9. Agreement and ability to store up to four sample kits in the refrigerator during the study
10. Agreement and ability to receive shipments at a mailing address that is not a post office box
11. Agreement and ability to have a mobile phlebotomist collect blood, stool, and saliva samples at home or at a place of their choosing at least every 4 weeks during phlebotomist business hours
12. Agreement to complete daily and weekly questionnaires

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
350

Key exclusion criteria
Current exclusion criteria as of 01/08/2022:
1.Has a diagnosis of ischemic/radiation colitis
2. Has a diagnosis of primary sclerosing cholangitis
3. Has a diagnosis of an abdominal abscess or perianal abscess requiring surgical intervention or antibiotic treatment within the past 3 months
4. Has a history of cancer, excluding non-melanoma skin cancer that was completely removed
5. Has a history of organ transplant
6. Diagnosis of, or treatment for, infectious colitis, such as CMV colitis or Clostridium difficile colitis, within the past 60 days
7. Hospitalization within the past 8 weeks
8. Participation in a treatment program for drug, alcohol, or chemical abuse in the past 6 months
9. Use of biologics for non-IBD conditions
10. Use of an immune-modulating medication treating a condition other than IBD or its complications
11. Planned IBD abdominal surgery
12. Participation in a clinical trial that involves blood draws, any treatment or procedure for IBD, or a change in IBD care within the past 3 months
13. Current participation in a clinical trial that involves blood draws, any treatment or procedure for IBD, or a change in regular IBD care, or intending to participate in such a trial within the next 12 months

———

Previous exclusion criteria:
1. Has a diagnosis of a non-IBD autoimmune condition
2. Has a diagnosis of indeterminate/ischemic/radiation colitis
3. Has a diagnosis of primary sclerosing cholangitis
4. Has a diagnosis of an abdominal abscess or perianal abscess in the past 2 years
5. For participants with CD: diagnosis of intestinal strictures or intestinal fistula
6. Has a history of cancer, excluding non-melanoma skin cancer that was completely removed
7. Has a history of organ transplant
8. Diagnosis of, or treatment for, infectious colitis, such as CMV colitis or Clostridium difficile colitis, within the past 60 days
9. Hospitalization within the past 8 weeks
10. Participation in a treatment program for drug, alcohol, or chemical abuse in the past 6 months

11. Use of biologics for non-IBD conditions
12. Use of an immune-modulating medication treating a condition other than IBD or its complications
13. Prior or scheduled IBD abdominal surgery
14. Participation in a clinical trial that involves blood draws, any treatment or procedure for IBD, or a change in IBD care within the past 3 months
15. Current participation in a clinical trial that involves blood draws, any treatment or procedure for IBD, or a change in regular IBD care, or intending to participate in such a trial within the next 12 months

Date of first enrolment
30/09/2022

Date of final enrolment
24/03/2023

Locations

Countries of recruitment
United States of America

Study participating centre
NA - No Physical sites
NA
NA
United States of America
NA

Sponsor information

Organisation
F. Hoffmann-La Roche Ltd

Sponsor details
1 DNA Way
South San Francisco
United States of America
94080
+1 888-662-6728
global-roche-genentech-trials@gene.com

Sponsor type
Industry

Website

www.roche.com/about_roche/roche_worldwide.htm

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

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

Intention to publish date
31/01/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement.

IPD sharing plan summary
Not expected to be made available