

# Protein biomarkers for assessing Inflammatory Bowel Disease (IBD) treatment efficiency

<b>Submission date</b> 21/12/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/06/2017	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Inflammatory bowel disease (IBD) is a group of common chronic disorders involving bowel inflammation. Ulcerative colitis and Crohn's disease are the most important conditions of this group. IBD is usually diagnosed in young adults. In most cases it is characterized by long remissions and incidental flareups usually requiring treatment. Currently there are up to 600,000 IBD patients in the UK. All of them are at risk of a possible relapse. Those developing relapses are treated, and treatment efficiency assessment is an important task in need of serious improvements. In addition, IBD diagnosis is not straightforward since patients with functional conditions, such as extremely common irritable bowel syndrome (IBS) have similar symptoms. For this reason invasive endoscopy is usually applied in the absence of efficient non-invasive diagnostic methods. DiagNodus Ltd has developed a new method of non-invasive collection of biological material from the anal area following a natural bowel movement. This simple procedure based on sample self-collection provides a clear advantage compared to stool sample collection. The material collected using the new procedure contains cells in abundance and can be easily applied to a range of biomarker detection-based diagnostic and monitoring applications in the area of colorectal disease. This is an initial study looking at how well protein biomarker measurements in a group of patients with confirmed IBD and a parallel group of patients with IBS can help detect and treat IBD.

### Who can participate?

Patients diagnosed with IBD and patients diagnosed with IBS

### What does the study involve?

Participants are provided with material collection kits and instructed to self-collect samples of excreted material (rectal mucus containing cells and cell fragments with varying degrees of faecal contamination) from the external anal area immediately following defaecation using soft swabs. Material collections should be performed at home without any preparation or dietary or lifestyle restrictions. Following initial sample collection before the start of the treatment IBD patients undergo routine therapeutic treatments, and a range of selected protein biomarkers are quantitatively assessed in samples obtained using the new procedure both before treatment and at different times following the start of the treatment.

What are the possible benefits and risks of participating?

The results of this initial study should identify the most suitable protein biomarker(s) for developing a point of care (POC) test for IBD detection, treatment efficiency assessment and long-term monitoring of IBD activity.

Where is the study run from?

St George's Hospital (UK)

When is the study starting and how long is it expected to run for?

January 2013 to July 2014

Who is funding the study?

DiagNodus Ltd (UK)

Who is the main contact?

Dr Alexandre Loktionov

alex.loktionov@diagnodus.com

## Contact information

### Type(s)

Scientific

### Contact name

Dr Alexandre Loktionov

### Contact details

DiagNodus Ltd

Bldg 280

Babraham Research Campus

Cambridge

United Kingdom

CB22 3AT

+44 (0)1223 497 181

alex.loktionov@diagnodus.com

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

96543

## Study information

Scientific Title

Evaluation of a new method of noninvasive material collection for protein biomarker detection as an approach to assessing inflammatory bowel disease treatment efficiency.

### **Study objectives**

It is suggested that detection of protein biomarkers of colorectal disease in non-invasively collected samples of colorectal mucocellular layer can provide a highly efficient and convenient method of diagnosing inflammatory bowel disease (IBD) and assessing individual responses of patients to applied IBD therapy.

The trial addresses an important clinical problem of assessing therapy efficiency in patients developing flareups of inflammatory bowel disease (IBD). Tests based on the use of disease activity biomarkers are rarely applied for this purpose, detection of calprotectin in stool being the only test of this type sometimes used, but not widely clinically accepted. Introduction of inflammation biomarker detection in non-invasively obtained material can revolutionise IBD therapy efficiency assessment providing a convenient tool for checking therapeutic effects of applied drugs and individualising therapeutic schemes. Introduction of this approach into clinical practice can improve the cost efficiency of IBD treatment. An additional dimension of the trial is provided by comparing biomarker measurement results obtained in IBD patients with similar measurements done in subjects with irritable bowel syndrome (IBS) and healthy volunteers in order to assess IBD diagnosis efficiency.

Although this clinical trial involves biological material collection from patients, the proposed way of collecting biological samples for the study is absolutely non-invasive and not associated with any potential harm. All subjects agreeing to participate in the trial are provided with material collection kits and instructed to self-collect samples of excreted material (rectal mucus containing cells and cell fragments with varying degrees of faecal contamination) from the external anal area immediately following defaecation using soft swabs. All study participants are given written instruction sets and requested to sign informed consent forms. Material collections should be performed at home without any preparation or dietary or lifestyle restrictions.

All individual records used in the study are carefully anonymised and coded in order to avoid any possibility of personal identification of study participants.

### **Ethics approval required**

Old ethics approval format

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

NRES Committee London - Queen's Square, 26/06/2012, ref: 12/LO/0237

### **Study design**

Longitudinal and case-control designs

### **Primary study design**

Observational

### **Secondary study design**

Both longitudinal and case-control designs are applied within the study

### **Study setting(s)**

Hospital

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

Diagnostic

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

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

Inflammatory bowel disease (IBD), irritable bowel syndrome (IBS)

### **Interventions**

Although the study is basically observational, non-invasive collection (self-collection by study participants) of diagnostically informative samples is undertaken.

### **Intervention Type**

Other

### **Primary outcome measure**

1. Confirmation of sample collection method acceptance by patients
2. Confirmation of high quality of the collected material
3. Confirmation of the validity of biomarker quantification in the collected material for diagnostic and monitoring purposes

### **Secondary outcome measures**

1. Selection of optimal biomarkers for IBD diagnosis
2. Selection of optimal biomarkers for IBD therapy efficiency assessment

### **Overall study start date**

16/01/2013

### **Completion date**

15/07/2014

## **Eligibility**

### **Key inclusion criteria**

1. Patients with active IBD requiring conservative treatment;
2. Patients with IBD in remission
3. Patients with IBS
4. Healthy volunteers (a smaller group)

### **Participant type(s)**

Mixed

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

120-200 (at least 120)

**Key exclusion criteria**

1. Concomitant colorectal disease other than IBD or IBS
2. Extensive colorectal surgery in the past

**Date of first enrolment**

16/01/2013

**Date of final enrolment**

01/06/2014

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**DiagNodus Ltd**

Bldg 280

Babraham Research Campus

Cambridge

United Kingdom

CB22 3AT

**Study participating centre**

**St George's NHS Trust**

Department of Gastroenterology

London

United Kingdom

SW17 0QT

## **Sponsor information**

**Organisation**

DiagNodus Ltd

**Sponsor details**

Bldg 280

Babraham Research Campus

Cambridge

Cambridge  
United Kingdom  
CB22 3AT  
+44 (0)1223 497 181  
alex.loktionov@diagnodus.com

**Sponsor type**

Industry

**Website**

www.diagnodus.com

**ROR**

<https://ror.org/04r796168>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Diagnodus Ltd

## Results and Publications

**Publication and dissemination plan**

One conference presentation so far:

Chhaya, V, Poullis, A, Bandaletova, T, Loktionov, A. (2014). Patient acceptability of a novel, non-invasive method of colonic sampling for biomarker analysis. Gut, 63 (Suppl. 1) A131 (PWE-022).

Further conference presentations and journal publications planned in 2015-2016

**Intention to publish date**

01/08/2015

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2017		Yes	No