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

Submission date 21/12/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/01/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 02/06/2017	**Condition category** Digestive System	[_] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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

Key secondary outcome(s))
1. Selection of optimal biomarkers for IBD diagnosis
2. Selection of optimal biomarkers for IBD therapy efficiency assessment

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
DiagNodus Ltd
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Babraham Research Campus
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Study participating centre
St George's NHS Trust
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Sponsor information

Organisation
DiagNodus Ltd

ROR
https://ror.org/04r796168

Funder(s)

Funder type
Industry

Funder Name
Diagnodus Ltd

Results and Publications

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?
Results article	results	01/05/2017		Yes	No