Clinical trial registration statement: The study was registered at clinicaltrials.gov, ID NCT02492555.

ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
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ClinicalTrials.gov ID: NCT02492555

Study Identification

Unique Protocol ID: 48121

Brief Title: Is Relapse Rate Reduced by Home Monitoring of IBD Patients Tightly or on Demand by FC and Disease Activity?

Official Title: Is Relapse Rate Reduced by Home Monitoring of IBD Patients Tightly or on Demand by FC and Disease Activity?

Secondary IDs:

Study Status

Record Verification: April 2017

Overall Status: Completed

Study Start: July 2015 [Actual]

Primary Completion: July 2016 [Actual]

Study Completion: July 2017 [Actual]

Sponsor/Collaborators

Sponsor: Nordsjaellands Hospital

Responsible Party: Sponsor

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved
Approval Number: 48121
Board Name: Danish Ethical committee
Board Affiliation: De Videnskabsetiske Komiteer for Region Hovedstaden
Phone: +45 3866 6395
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De Videnskabsetiske Komiteer for Region Hovedstaden
Center for Sundhed
Kongens Vænge 2

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Data Monitoring: Yes

FDA Regulated Intervention: Yes

Section 801 Clinical Trial: No

Study Description

Brief Summary: The purpose of this study is to determine if the IBD patient doing home monitoring by web app's for disease activity (DA) and fecal calprotectin (FC) on demand (OD), compared with patients doing home monitoring scheduled interval combined with "on demand"(SI+OD) (every 3.month).

Will home monitoring of DA and FC OD vs SI+OD reduce frequency of relapse in one year follow up? Is the frequent FC measurement in SI+OD test group predictive of an early recognition of relapse, and thus help change the naturel course of disease? Will home monitoring of DA and FC in OD vs SI+OD change the course of the disease in terms of disease activity, spread of the disease, hospitalizations and number of hospitalization days, required surgery and outpatient visits? Is there a difference in patients' compliance with treatment plan between OD vs SI+OD ? Is there difference in patients-adherence between OD vs SI+OD ?

Detailed Description: Detailed Description Among 2.500 IBD patients the investigators will consecutively from the Gastroenterology out-patient clinic at North Zealand University Hospital recruit in total 120 in the study.

At the out-patient consultation IBD patients will be informed about the project and the IBD eHealth nurse ensures that no exclusion criteria met by the patient.

Inclusion criteria: IBD patients in remission, SCCAI ≤ 2 (Simple Clinical Colitis Activity Index)) or HBI < 5 (Harvey & Bradshaw Activity Index) or in mild to moderate disease activity (SCCAI 3-4, HBI < 16) IBD patients who can read, speak and understand Danish IBD patients that can take advantage of the Internet and wireless network 18years or older.

Exclusion criteria: IBD patients with severe disease activity HB > 16 SCCAI ≥ 5) IBD patients with social, medical or psychological issues of a more complex character IBD patients with particularly complex issues such as drug and alcohol problems, severe mental / psychiatric disorders and / or serious social impact.

IBD patients who cannot attend due language barrier or cognitive disorder. Age less 18. When the patient has agreed to participate in the study, randomized to either OD or SI OD 3. Months (SI group):

Patients log in at www.noh.constant-care.dk at least once every 3rd months throughout the project period of 12 months. When the patient log in to the telemedicine platform following scoring must be filled out:

1. - Disease activity, respectively SCCAI or HBI.
2. - Quality of life assessment, in s - IBDQ every 3rd months.
3. - FACIT (Fatigue score)
4. - MARS (Medical Adherence Rating Scale)

- FC, fecal calprotectin mg / kg feces) with SMART phone, rapid home test. If the patients prefer to send the feces test, it will be tested in the Gastro unit lab. at the hospital with SMART phone.

The results of the scoring systems will appear to the health professionals and patients in a traffic light turning into red, yellow and green.

If the patient experiences a recurrence of the disease, it moves from green to either yellow or red area in the traffic graph, and patient will further be instructed to contact Gastro medical clinic project nurse for an early consultation and decision on further treatment initiative. This will also be indicated at the patient's website. If alarm symptoms occurs patients are instructed to contact the project nurse. Thus patients are treated in accordance to national and international guideline. By screening of the inflammation burden the decision is moving forward.

On Demand Group:

Patients log in on demand,detects disease activity, quality of life and FC at the start, and subsequently when needed and at the end of the study (12 months).

At relapse disease activity score and FC is settled and repeated no later than 7 days here after at remission a new DA and FC test should be performed to verify the remission.

Statistical considerations:

Randomization Suitable (N = 120) will be randomized to one of the test groups by sealed envelope principle.

Material size calculation:

A relapse last in median 18 days in patients with inflammatory bowel disease, but the variance is large (10-50 days). During one year of a prevalent IBD patient group 50 % of a patient population will experience a relapse. To assess whether fewer patients experience true "red" indicated by relapse via (TIBS) Feces Calprotectin (FC) and disease activity in group 1 vs. Group 2 respectively, the sample size has been depicted from TIBS and a statistically significance (α) of 0.05 , and test force of (β) of 0.8 .

This means that there must be included 53 individuals in each group, which means that there must be included a total of 106. Thus the investigators have chosen to include 120 patients, 60 in each group in order to correct for a possible of small drop out in each group.

Conditions

Conditions:	Inflammatory Bowel Disease
Keywords:	IBD Telemedicine At-home monitoring Disease activity fecal calprotectin

Study Design

Study Type:	Interventional
Primary Purpose:	Health Services Research
Study Phase:	N/A
Interventional Study Model:	Parallel Assignment
Number of Arms:	2
Masking:	None (Open Label)
Allocation:	Randomized

Enrollment: 120 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Scheduled (SI) "Scheduled" means screening every 3rd month (home FC and DA) plus when needed and upgrade of ususal treatment	SI A routine scheduled (SI) screening of FC and DA every 3rd month
Active Comparator: On Demand (OD) On "Demand" means screening of home FC and DA when the patients feel for it and upgrade of usual treatment	OD A screening of FC and DA on demand (OD)

Outcome Measures

Primary Outcome Measure:

1. Total Inflammation Burden Scoring (TIBS)
   The outcome measure of TIBS (FC (ELISA Smartphone test)and Disease Activity (Simple Clical Colitis Activity Index or Harvey-Bradshaw Index) has been chosen as endpoint for comparing the two screening methods in relation to relapse rate

   [Time Frame: 1 year]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- IBD patients in remission, SCCAI ≤ 2 (Simple Clinical Colitis Activity Index)) or HBI < 5 (Harvey & Bradshaw Activity Index) or in mild to moderate disease activity (SCCAI 3-4, HBI < 16)
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- IBD patients that can take advantage of the Internet and wireless network 18 years or older

Exclusion Criteria:

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- IBD patients with particularly complex issues such as drug and alcohol problems, severe mental / psychiatric disorders and / or serious social impact.
- IBD patients who cannot attend due language barrier or cognitive disorder.
- Age less 18.
- When the patient has agreed to participate in the study

Contacts/Locations

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