Value-based healthcare for Inflammatory Bowel Disease: improving (cost-)effectiveness

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21751

Source
NTR

Brief title
IBD Value

Health condition

Inflammatory bowel disease, Ulcerative colitis, Crohn's disease

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland
Source(s) of monetary or material Support: Stichting Onderzoek & Ontwikkeling Franciscus; Bevordering Onderzoek Franciscus

Intervention

Outcome measures

Primary outcome

Patient-reported, disease control, measured using the IBD-Control questionnaire (sum of questions 1,2 and 3)

Secondary outcome

The rest of the IBD Standard Set of outcomes, as defined by by ICHOM, which concerns:
Incidence of mortality and proportion attributable to IBD
Proportion in remission, both clinician-reported (biochemical, histological, endoscopic, radiological) and patient-reported (Manitoba IBD Index/MIBDI)
Incidence of colorectal cancer, with incidence of preceding colorectal dysplasia and proportion participating in a surveillance program.
Incidence of anemia
Number of emergency room visits
Number and length of hospital admissions
Incidence of complications of any intervention of IBD
Incidence of any steroid use and long-term steroid use
Incidence of fistulae symptoms
BMI as a proxy for nutritional status

Quality of life as defined by the EQ-5D-5L (both visual analog scale as well as the Dutch tariffs) and the PROMIS-10 General Health
Patient experience as defined by the modified and translated Picker questionnaire for use in Dutch healthcare
Costs from a societal perspective (healthcare costs, productivity costs and patient costs) as advised by the Dutch healthcare authority
Cost-effectiveness of the interventions, as defined by the incremental cost-effectiveness ratio

Study description

Background summary

Rationale: Treatment of inflammatory bowel disease (IBD) with biologic agents is complex and the cost is continuing to rise. One approach to tackling these issues may well be value-based healthcare (VBHC) that measures outcomes that matter most to patients, namely, patient-reported outcome measures (PROMs), patient-reported experience measures (PREMs) and clinical outcome measures. VBHC effectiveness requires continuous measurement, comparison and response to these outcome measures, and reducing variation in treatment practice. From this perspective we aim to study an uniform care pathway for the treatment of IBD with biologic agents.

Objective:
The main objective of the study is to evaluate the effect of a care pathway on the health outcomes of IBD patients treated with a biologic agent. Secondary objectives are to:
• Assess regional variation in outcomes and costs of the treatment of IBD with biologic agents;
• Uncover points of improvement in the care of IBD patients;
• Create and implement a care pathway for the treatment of IBD with biologic agents based

on scientific evidence and adapted to the local context;
• Evaluate the cost-effectiveness of the care pathway.

Study design: The study is designed as a multicentre open cohort with a quasi-experimental design leveraging a change in standard of care. The study duration of 27 months will be divided in a baseline measurement (12 months), implementation period (3 months) and evaluation of the care pathway (12 months).

Study population: Patients with an IBD diagnosis of at least 3 months, over the age of 18 years, and treated with a biologic agent in one of the 8 participating hospitals.

Intervention: Implementation of a uniform care pathway

Main study parameters:
Primary outcomes: IBD-Control-8 score
Secondary outcomes: The rest of the ICHOM IBD Standard Set, cost-effectiveness, patient experiences

Study objective

The first hypothesis is that there is variation in the treatment and follow-up of IBD patients between providers and consequently in the outcomes of care. The second hypothesis is that the implementation of a uniform care pathway for the treatment of IBD with biologic agents will reduce negative variations in care and subsequently improve health outcomes and lower costs.

Study design

In the first 12 months, the current situation will be assessed to establish the baseline, and subsequently, the care pathway will be implemented during a period of 3 months in six of the participating hospitals. A comprehensive evaluation of the care pathway will be done 12 months after implementation.

The demographics questionnaire will be administered once, at inclusion into the cohort, some of the questions will be updated yearly. The SCQ will be administered at the start of the study and every 12 months from the start of the study. The EQ-5D-5L, IBD-Control, Manitoba IBD Index and the PROMIS-General Health (PROMIS-GH) will be administered at the start of the study and at every 6 month mark.

Patient experience questionnaires will be distributed once per year, after an outpatient clinic visit.

Chart and administrative data will be gathered in half year periods.

Intervention

The care pathway will contain indications for starting, switching and stopping biologic agents,

and recommendations for follow-up (laboratory tests, colonoscopy, etc).

Contacts

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Eligibility criteria

Inclusion criteria

Treated in one of the eight hospitals
At least eighteen years of age
Have had a diagnosis of IBD for at least three months
Receive a biologic agent or tofacitinib as treatment for IBD. These are the biologics currently registered for the treatment of IBD (infliximab, adalimumab, golimumab, vedolizumab, ustekinumab), and new treatments registered during the study period.

Exclusion criteria

Insufficient mastery of the Dutch language to fill in the questionnaires
No access to the internet to fill in the questionnaires

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2020
Enrollment:	3200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Data will be available on reasonable request

Ethics review

Positive opinion

Date:	09-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8276
Other	METC Erasmus MC : MEC-2020-0275

Study results