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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21751

Bron
NTR

Verkorte titel
IBD Value

Aandoening

Inflammatory bowel disease, Ulcerative colitis, Crohn's disease

Ondersteuning

Primaire sponsor: Franciscus Gasthuis & Vlietland
Overige ondersteuning: Stichting Onderzoek & Ontwikkeling Franciscus; Bevordering Onderzoek Franciscus

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

The care pathway will contain indications for starting, switching and stopping biologic agents, and recommendations for follow-up (laboratory tests, colonoscopy, etc).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2020
Aantal proefpersonen:	3200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Data will be available on reasonable request

Ethische beoordeling

Positief advies

Datum:	09-01-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten