Characterization of Inflammatory Cell Subpopulations of Gut Associated Lymphoid Tissue and Peripheral Lymph Nodes in Inflammatory Bowel Disease

Gepubliceerd: 07-07-2021 Laatst bijgewerkt: 18-08-2022

We hypothesize that 1) GALT and peripheral LN are involved in IBD pathophysiology, and 2) GALT and peripheral LN are involved in anti-drug antibody formation, and thereby loss of response to therapy.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27715

Bron
NTR

Verkorte titel
Goldeneye

Aandoening

Inflammatory bowel disease; Crohn's disease and Ulcerative colitis

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: Amsterdam UMC, location AMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Frequencies and phenotype of immune cell populations in GALT in active and inactive IBD
2.Differences in immune cell populations (frequency, phenotype, cytokine production, genetic, epigenetic and transcriptional alterations) and stromal cells in GALT compared to peripheral lymph nodes

Toelichting onderzoek

Achtergrond van het onderzoek

One of the biggest barriers to progress towards better treatments in inflammatory bowel disease (IBD) is 1) our lack of understanding of the disease etiology and 2) our lack of understanding the mechanisms involved in response or lack/loss of response to treatments, such as the development of anti-drug antibodies. The gut associated lymphoid tissue (GALT) as well as peripheral lymph nodes (LN) are lymphoid structures that play an important role in and antibody formation and are involved in shaping intestinal and peripheral immunity. It is however unknown whether and how these lymphoid structures are involved in IBD etiology and whether they are involved in anti-drug antibody (ADA) formation. We hypothesize that 1) GALT and peripheral LN are involved in IBD pathophysiology, and 2) GALT and peripheral LN are involved in anti-drug antibody formation, and thereby loss of response to therapy.

Doel van het onderzoek

We hypothesize that 1) GALT and peripheral LN are involved in IBD pathophysiology, and 2) GALT and peripheral LN are involved in anti-drug antibody formation, and thereby loss of response to therapy.

Onderzoeksopzet

1 time point only, baseline

Onderzoeksproduct en/of interventie

participating IBD patients and controls will undergo inguinal lymph node biopsy sampling and blood sampling. In addition, in a subgroup of IBD patients requiring gastro-intestinal surgery with bowel resection, mesenteric lymph nodes will be obtained as well as Peyer’s patches, which will be collected from the resected intestinal segment. In addition, in the patients undergoing cholecystectomy mesenteric lymph nodes will be collected.

Contactpersonen

Publiek

Amsterdam UMC, location AMC
Maarten Pruijt

0650091289

Wetenschappelijk

Amsterdam UMC, location AMC
Maarten Pruijt

0650091289

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria IBD patients:
- Age 18-80 years
- Additional for aim 1 (GALT tissue sampling): Patients with CD undergoing ileocecal resection because of (inflammatory or fibrotic) stenosis or extensive inflammation or therapy refractory disease
Inclusion criteria healthy controls (Aim 1)
- Patients undergoing cholecystectomy in the non-acute setting (symptomatic gall stone disease), without active inflammation
- Negative for inflammatory bowel pathologies. - Age 18-80 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria IBD patients:
- Patients, who are not able to provide informed consent.
- History of malignancy
- Viral or bacterial infection within the past 4 weeks
- Patients using anticoagulant therapy
- Present or previous use of systemic corticosteroids less than 28 days before enrollment

- For aim 1: Present or previous use up to 3 months before enrolement of general immunosuppressive agents (e.g. Azathioprine, Methotrexate, Mycophenolate Mofetil) or biological treatments

Exclusion criteria control patients (undergoing cholecystectomy (Aim 1):
- Presence of intestinal inflammatory conditions (e.g. active cholecystitis)
- Presence of inflammatory bowel disease
- Individuals using anticoagulant therapy
- Present or previous use of systemic glucocorticoids less than 28 days before enrolment
- Present or previous use of experimental drugs
- Present or previous treatment with any cell depleting therapies, including investigational agents
- Presence of any disease for which study subjects need chronic or intermittent immunosuppressive therapy (e.g. prednisolone).
- History of chronic viral infection
- Recent (<1 week) bacterial or viral infection

- History of autoimmune disease
- History of malignancy
- Individuals, who are not able to provide informed consent

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	29-06-2021
Aantal proefpersonen:	64
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-07-2021
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	NL9591
Ander register	METC AMC : METC 2021_039

Resultaten