Diet for Induction and Maintenance of Remission and Re-biosis in Crohn's disease

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

Samenvatting

ID

NL-OMON23154

Bron
NTR

Verkorte titel
DIETOMICS

Aandoening

Crohn's Disease

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: Wolfson Medical Center, Israel

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary end point will be ITT, sustained Corticosteroid-free remission at week 14 (defined as Pediatric Crohn Disease Activity Index- PCDAI ≤10 without exposure to systemic steroids).

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:
Exclusive enteral nutrition (EEN) is an established but difficult to perform method for induction of remission and is not practical or effective for maintenance of remission. It entails drinking a liquid medical formula for 8 weeks as the sole intake of food. Refusal to use or to adhere to this therapy is not uncommon and leads to use of other non- dietary strategies in children including steroids and immunosuppression. Partial enteral nutrition (PEN) appears to have some benefit in maintenance of remission in adults but paediatric data are conflicting. There is no prospective pediatric controlled trial to provide evidence. The Crohn's Disease Exclusion Diet (CDED) with partial enteral nutrition has been shown to be effective for induction of remission in children with mild to moderate disease. We have developed a maintenance strategy based on the CDED that appears to maintain remission while allowing increased access to table foods over time.

Objective of the study:
To prove that sustained clinical remission can be maintained at week 14 with a new dietary strategy that involves only 2 weeks of EEN with Modulen and 22 weeks of an exclusion diet involving selected table foods.
We hypothesize that use of EEN for only 2 weeks followed by partial enteral nutrition with the CDED diet with PEN will be superior in sustaining Corticosteroid-free remission by week 14 compare to 8 weeks of EEN followed by PEN and free diet, and that this remission will be maintained through week 24 while the diet is maintained. From a translational viewpoint, we intend to compare the effects of dietary therapy on the microbiome, including microbial function and mucosa associated bacteria, between patients using standard EEN and free diet and those on modified EEN and CDED with PEN. We will also compare changes in microbiome to healthy controls, siblings and parents. We further hypothesize that the CDED will promote butyrate producing species while EEN will reduce these species.

Doel van het onderzoek

We hypothesize that use of EEN for only 2 weeks followed by partial enteral nutrition with the CDED diet with PEN will be superior in sustaining Corticosteroid-free remission by week 14 compare to 8 weeks of EEN followed by PEN and free diet, and that this remission will be maintained through week 24 while the diet is maintained. From a translational viewpoint, we intend to compare the effects of dietary therapy on the microbiome, including microbial function and mucosa associated bacteria, between patients using standard EEN and free diet and those on modified EEN and CDED with PEN. We will also compare changes in microbiome to healthy controls, siblings and parents. We further hypothesize that the CDED will promote

butyrate producing species while EEN will reduce these species. In addition, we hypothesize that patients with genetic predisposition will be less responsive to dietary intervention.

Onderzoeksopzet

week 0,2,(3 phone visit),5 (optional),8, 9 (phone visit),14,15,18 (call or email),24,52

Onderzoeksproduct en/of interventie

Modified CDED

Contactpersonen

Publiek

AmsterdamUMC
Charlotte Verburgt

0650063243

Wetenschappelijk

AmsterdamUMC
Charlotte Verburgt

0650063243

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Established diagnosis of Crohn's disease.
2. Patients with mild to severe active Crohn's disease (15≤PCDAI≤47.5)
3. Ages 8-18
4. Duration of disease ≤ 36 months
5. Active inflammation (CRP≥0.6 mg/dL or ESR≥20 or Calprotectin≥200 mcg/gr during screening
6. Patients with B1, P0 uncomplicated disease at enrollment
7. Patients with disease defined as L1, L4, L3 or L2 limited to cecum, ascending or transverse

colon or L2 with leftsided disease with terminal ileum or small bowel involvement in the past by the Paris classification (patients with macroscopic disease)
8. Signed informed consent

Inclusion criteria comments:
1. Patients with stable medication (IMM/5ASA) use or no medication use for the past
2. Patients with few aphthous ulcers in the rectosigmoid only can be enrolled as L2

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with very mild disease (PCDAI 12.5-15) or very severe disease (PCDAI >47.5)
2. Pregnancy
3. Patients who have disease confined to the colon involving the descending colon, rectum or sigmoid colon and no prior history of small bowel involvement
4. Patients who have active extra intestinal disease (such as arthritis, uveitis, pyoderma gangresom, erythemanodosum, etc.)
5. Patients with complicated disease (B2, B3)
6. Patients with recent onset use of an immunomodulator <8 weeks, or dose change in past 8 weeks.
7. Patients with past or current use of biologics, or patients who currently use systemic steroids or used steroids over the last 8 weeks
8. Patients who have active perianal disease (active fistula or abscess)
9. Patients who have positive stool cultures with relevant pathogens, or positive tests for parasites or C. difficile. Stool tests are mandatory only if diarrhea is present.
10. Patients with fever > 38.3
11. Documented milk protein allergy

Exclusion criteria comments:
1. Aphthous stomatitis is not an exclusion criterion. Isolated aphthous ulcers of the rectosigmoid need not be excluded as left sided L2 only
2. Patient may receive a stable dose immunomodulator or start thiopurines at or after week 4 or Methotrexate at week 6, since the effect of thiopurine starts after 8 weeks and that does not affect the primary endpoint
remission at week 8.
3. Patients are allowed use of Omeprazole if ulcers or erosions are present in the stomach or duodenum.
4. Patients may receive antibiotics for intercurrent infections for up to 10 days with the exception of quinolones,metronidazole, rifaximin or oral vancomycin; antibiotics used must be registered in the CRF.
5. Patients with skin tags or fissures can be enrolled.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2020
Aantal proefpersonen:	10
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:	21-04-2021
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	NL9417
Ander register	METC AMC : METC 2020_104

Resultaten