# Caloric and protein restriction diet for induction treatment of Crohn's disease

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To assess the efficacy of a calorie and protein restricted (CRPR) diet for induction of remission in CD.

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

## Samenvatting

### ID

NL-OMON22551

**Bron**
Nationaal Trial Register

**Verkorte titel**
TOCDI

**Aandoening**

IBD, Crohn's disease

### Ondersteuning

**Primaire sponsor:** none
**Overige ondersteuning:** none

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Proportion of patients with clinical remission after 4 weeks of dietary intervention. Clinical remission will be defined as a Harvey Bradshaw Index (HBI) < 5.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Many patients with inflammatory bowel disease (including Crohn’s disease and Ulcerative Colitis) associate dietary components with disease activity. Although several dietary interventions have been investigated for the treatment of Crohn’s disease (CD), study results have been mixed. At the Erasmus MC, Department of Surgery, an integrated calorie and protein restriction (CRPR) diet has been developed. This diet was shown to be safe and feasible in healthy kidney donors and morbidly obese patients for five consecutive days prior to surgery (METC number 2012-134). The CRPR diet is now being tested in metastatic colorectal cancer patients receiving irinotecan, to optimize anti-tumor effects and survival (METC number 15-710). In mouse models, the CRPR diet results in a reduction of acute and chronic pro-inflammatory responses, including a reduction of inflammatory mTOR signaling in a leptin-dependent manner, and reduction of IL6 and TNFα levels. As these inflammatory responses play a pathogenic role in IBD, a CRPR diet may also be effective for treatment in IBD. In addition, diets are known to modulate the microbiome, and as dysbiosis of the intestinal microbiota is also assumed to contribute to CD pathology, we speculate that modulation of the microbiome through the CRPR diet is another mechanism of action potentially contributing to the induction of remission in CD.

This study will investigate a calorie restriction/protein restriction (CRPR) diet, consisting of 70% of the individual’s required calories and ~20% of the individual’s protein requirement, based on basal metabolic rates and on the daily energy requirements. An induction phase will consist of 4 days diet at week 1, 3 days at week 2, 3 days at week 3 and 3 days at week 4. CD patients with endoscopically mild to moderate disease will be included. Patients will be randomized 1:1 to either dietary intervention or budesonide 9mg induction therapy for four weeks. The dietary intervention will consist of 4 days diet at week 1, 3 days at week 2, 3 days at week 3 and 3 days at week 4. Clinical efficacy of CRPR diet for induction of remission will be assessed after these four weeks. Blood and stool samples will be collected for molecular and microbial (microbiome) analysis.

### Doel van het onderzoek

To assess the efficacy of a calorie and protein restricted (CRPR) diet for induction of remission in CD.

### Onderzoeksopzet

baseline, week 2, week 4

### Onderzoeksproduct en/of interventie

The CRPR diet consists of an estimated 70% of the individuals required calories and 20% of

the individuals protein (12), based on the basal metabolic rates and on the daily energy requirements (DER) as calculated with the Harris-Benedict equation (14) and with the BODPOD (the Gold Standard Body Composition Tracking System is an air displacement plethysmograph which uses whole-body densitometry to determine body composition (fat and fat-free mass) in adults (18, 19)l. The Harris-Benedict equation takes into account sex, height, age, body weight and estimated activity level. Normal protein intake is set at 20% of the total calories based on the DER. To facilitate the dietary requirements, participants will receive calorie- and protein-restricted powder shakes (Scandishake® Mix) as the main component of the diet, which can be supplemented with a limited amount of protein-restricted products (mainly fruits and vegetables) until the desired individual energy content of the diet is reached.

# Contactpersonen

## Publiek

## Wetenschappelijk

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Crohn's disease

- Active mild to moderate disease (defined as an endoscopic SES-CD score ≥ 6 or in case of exclusive ileal disease ≥ 4, after ileocoecal resection a Rutgeert's score >i2 and a HBI score between 5 and 10)

- Age between 18 ¨C 70 years at baseline

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- BMI: <18.5, >35

- Weight loss of >5% within one month or >10% within 6 months prior to the study

- Use of pro- and antibiotics in 6 weeks prior to start of the study

- Known allergy/intolerance to any of the ingredients in the diets

- Known malignancy or dysplasia

- Pregnancy, lactation

-Risk of malnutrition as determined by renal insufficiency, renal or electrolyte abnormality (serum creatinine >2x upper limit of normal (ULN); eGFR < 30 mL/min Serum potassium outside the 3,5- 5,0 mmol/l range and serum sodium outside the 135-145 mmol/l range)

- Presence of toxins or other signs of infectious agents in stool sample
(i.e. clostridium, salmonella, shigella, yersinia or campylobacter)

- Insulin-dependent diabetes mellitus

- Patients using oxygen and not able to stop for 30 minutes

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Actieve controle groep |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-06-2018 |
| Aantal proefpersonen: | 30 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 17-09-2018 |
| 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 | NL7418 |
| NTR-old | NTR7651 |
| Ander register | : METC NL60259.078.16 |

# Resultaten