# SYNTREG

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON22553

**Source**
NTR

**Brief title**
SYNTREG

**Health condition**

Immune modulatory activity of a pre-probiotic blend in healthy adult volunteers

### Sponsors and support

**Primary sponsor:** Nutricia Research BV
**Source(s) of monetary or material Support:** Nutricia Research BV

### Intervention

### Outcome measures

**Primary outcome**

Change from baseline in IL-10 production and/or forkhead box protein 3 (Foxp3) expressing cells after 8 weeks of daily study product intake.

**Secondary outcome**

- Change from baseline in IL-10 production and/or Foxp3 expressing cells after 2 weeks of daily study product intake

- Change from baseline in the levels of several cytokines and prostaglandin E2 (PGE2) and fatty acid composition after 2 and 8 weeks of daily study product intake

- Adverse events (AEs), gastrointestinal (GI) tolerance, stool frequency, consistency and colour.

# Study description

### Background summary

Not yet available

### Study objective

H0: The effect of product A is equal to the effect of product B with respect to change from baseline after 8 weeks of study product intake in IL-10 production [pg/mL] AND in Foxp3 expressing cells.

H1: The effect of product A is unequal to the effect of product B with respect to change from baseline after 8 weeks of study product intake in IL-10 production [pg/mL] OR in Foxp3 expressing cells.

### Study design

V1 ( Day 1); V2 (Day 14); V3 (Day 56)

### Intervention

Duration of intervention: 8 weeks

Intervention group: A pre-probiotic blend and maltodextrose

Control group: maltodextrose

# Contacts

**Public**
Nutricia Research B.V.

Monique Visser
PO Box 80141

Utrecht 3508 TC
The Netherlands
+31-30-2095000
**Scientific**
Nutricia Research B.V.

Monique Visser
PO Box 80141

Utrecht 3508 TC
The Netherlands
+31-30-2095000

# Eligibility criteria

## Inclusion criteria

- Age ≥ 18 and ≤ 40 years

- Written informed consent

- Willingness and ability to comply with the study protocol

- Body Mass Index (BMI) ≥ 18.5 and ≤ 24.9 kg/m2

- Non-smoking or stopped smoking for at least 3 months prior to Visit 1 (randomisation)

- Regular stool (stool frequency of at least 1 stool in 3 days)

- Judged by the investigator to be in good health

## Exclusion criteria

- Any medical condition that interferes with GI function (e.g irritable bowel syndrome, short bowel syndrome, inflammatory bowel disease, gastric ulcer, gastritis (gastro)enteritis)

- Constipation and/or diarrhoea within 1 week prior to Visit 1 (randomisation)

- Any known allergy and/or intolerance (e.g. coeliac disease, gluten intolerance, allergy to one of the ingredients of the study product)

- Any known renal or hepatic failure

- (History of) any immunological disease and/ or immunodeficiency

- (History of) any cancer with the exception of basal cell carcinoma

- Use of prokinetics, laxatives, antidiarrhoeals, corticosteroids, proton-pump inhibitors (or other gastric acid reducers), immunosuppressants or any active allergy treatment within 3 weeks of Visit 1 (randomisation)

- (History of) any chemotherapy or immunotherapy

- Use of antibiotics within 3 months of screening

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 21-02-2017 |
| Enrollment: | 30 |
| Type: | Actual |

## IPD sharing statement

**Plan to share IPD:** No

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 14-02-2017 |
| 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 | NL6095 |
| NTR-old | NTR6242 |
| Other | Stichting BEBO : 15AL89652 |

# Study results

**Summary results**
No