# Tolerance of regular meal intake with mycoprotein

Published: 01-05-2020
Last updated: 10-04-2024

The primary objective is to investigate gastro-intestinal complaints during 18 day Fermotein consumption. Secondary objectives are to assess blood based parameters related to general health. Outcomes will be part of a novel food dossier.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON50091

**Source**
ToetsingOnline

**Brief title**
TOMMY

### Condition

- Other condition
- Gastrointestinal disorders

**Synonym**
intestinal discomfort and general health

**Health condition**

overige gezondheids parameters

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Bioscienz
**Source(s) of monetary or material Support:** Bioscienz

## Intervention

**Keyword:** mycoprotein, Safety, Tolerance

## Outcome measures

### Primary outcome

The primairy study parameter is frequency and severity of gastro-intestinal complaints.

### Secondary outcome

Secondary outcomes are health parameters derived from blood samples taken before and after the intervention.Additional samples (including stool samples) will be collected to enable future measurements when requested by the assessment committee of the novel food dossier

# Study description

### Background summary

Mycoprotein is a protein source derived from fungi, especially as produced for human consumption. It is high in protein, high in fiber, low in saturated fat and contains no cholesterol. Their functional properties and nutrient content makes them ideal to use as an ingredient for meat alternatives. Fermotein is such a mycoprotein type novel food source.

### Study objective

The primary objective is to investigate gastro-intestinal complaints during 18 day Fermotein consumption. Secondary objectives are to assess blood based parameters related to general health. Outcomes will be part of a novel food dossier.

### Study design

The study has a randomised parallel design. Two different treatments will be evaluated e.g. a 18-day intervention with Fermotein based meals (bread and an occasional burger) and a 18-day intervention with matching control meals. At start and at the end of the intervention we will collect a blood, faecal and urine sample. Questionnaires about gut complaints, stool consistency and frequency, wellbeing, health complaints or other adverse effects will be collected daily during intervention and up to two days after intervention.

### Intervention

Subjects will daily consume a lunch meal containing approximately 11g of Fermotein or control for 18 days.

### Study burden and risks

This study is not related to a specific group. There are minor risks for the participants of this study. There are no direct benefits for the participants. Fermotein has been analysed thoroughly on safety parameters and no harm is expected. The total amount of blood collected during the study is low and therefore not expected to cause any problems. Study subjects that will participate in the study will invest approximately 30 hours during the trial and need to visit the research facility daily during working days for three weeks

## Contacts

**Public**
Bioscienz

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NL
**Scientific**
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Apparently healthy men and women
Age between 18 and 70 years
Body mass index (BMI) between 18.5 and 29.9 kg/m2

## Exclusion criteria

* Any metabolic, gastrointestinal, inflammatory or chronic disease (such as diabetes, anaemia, hepatitis, cardiovascular disease)
* History of gastro-intestinal surgery or having (serious) gastro-intestinal complaints
* History of liver dysfunction (cirrhosis, hepatitis)
* Kidney dysfunction (self-reported)
* Use of medication that may influence the study results, such as gastric acid inhibitors or laxatives
* Reported slimming or medically prescribed diet
* Current smokers
* Alcohol intake *4 glasses of alcoholic beverages per day
* Pregnant, lactating or wishing to become pregnant in the period of the study (self-reported)
* Abuse of illicit drugs
* Having food allergies
* Participation in another clinical trial at the same time
* Being an employee of the department Consumer Science & Health group of Wageningen Food & Biobased Research

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 12-10-2020 |
| Enrollment: | 24 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 01-05-2020 |
| Application type: | First submission |
| Review commission: | METC Wageningen Universiteit (Wageningen) |

# 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 |
| --- | --- |
| Other | het traject loopt |
| CCMO | NL72349.081.19 |