# Correlation between symptoms and the presence of gluten immunogenic peptides in faeces and urine after single dose gluten provocation in patients with coeliac disease*

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To assess the correlation between the presence of GIP in urine/ faeces and symptoms after a single dose gluten provocation (mimicking the daily risk of gluten ingestion) in patients with coeliac disease adhering to a strict gluten-free diet.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Malabsorption conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON43024

**Source**
ToetsingOnline

**Brief title**
Gluten intake, symptoms and detection of gluten in urine and feces

### Condition

- Malabsorption conditions

**Synonym**
Celiac disease

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Rijnstate Ziekenhuis
**Source(s) of monetary or material Support:** Geen financiering

## Intervention

**Keyword:** Celiac disease, Gluten, Symptoms

## Outcome measures

### Primary outcome

The correlation between the presence of GIP in urine/ faeces and symptoms after

gluten provocation

### Secondary outcome

None

# Study description

### Background summary

Up to 20 percent of coeliac patients continue to experience symptoms despite reporting strict adherence to gluten-free diet. Persistent symptoms may be related to cryptogenic gluten intake. Recent studies found gluten immunogenic peptides (GIP) in feces of 30 percent of patients reporting strict adherence.

### Study objective

To assess the correlation between the presence of GIP in urine/ faeces and symptoms after a single dose gluten provocation (mimicking the daily risk of gluten ingestion) in patients with coeliac disease adhering to a strict gluten-free diet.

### Study design

prospective, single blind, placebo controlled cross-over trial

### Intervention

During a 12 week period, both groups will take capsules on 6 time points

containing either gluten (3 times) or placebo (rice-starch) (3 times) with a 2 week washout period

### Study burden and risks

The risks mimic daily life risk of cryptogenic gluten ingestion which can cause temporary coeliac symptoms such as bloating, abdominal distress and diarrhea. Patient only need to visit ones to discuss study participation. No blood samples will be taken. Patients have to collect 7 urine and feces samples which will be collected at their homes by a trial nurse. Patients have to fill in short forms addressing coeliac complaints and dietary issues.

## Contacts

**Public**
Rijnstate Ziekenhuis

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

## Inclusion criteria

Patients with biopsy proven coeliac disease, Marsh IIIA or higher at time of diagnosis, adhering to a gluten-free diet and aged 18 years or older are eligible if:

- They report clear symptoms on gluten exposure
- They report excellent or no problems with dietary adherence (score 13 or less) on the Celiac Disease Adherence Test (CDAT)(8) (Appendix 2)
- They report scores resembling clinical remission (score 30 or less) on the Celiac Symptom Index (CSI)(9) (Appendix 3)
- Serum TTG and EMA levels are non-detectable during gluten-free diet
- Negative GIP in urine/ faeces at the start of this study

## Exclusion criteria

Patients will be excluded if;
- They report other CDAT and/or CSI scores
- They are pregnant
- They have known gastroenterological co-morbidity
- They have malignant disease
- They use painkillers or other drugs to reduce symptoms

# Study design

## Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 14-12-2018 |
| Enrollment: | 40 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 10-07-2018 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 14-03-2019 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 |
|---|---|
| CCMO | NL59453.091.16 |