# Assessment of Responsiveness to Treatment of the Experience Sampling Method (ESM) in Irritable Bowel Syndrome using linaclotide

Published: 14-06-2017
Last updated: 15-04-2024

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Gastrointestinal motility and defaecation conditions |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON50476

**Source**
ToetsingOnline

**Brief title**
ESM Linaclotide

### Condition

- Gastrointestinal motility and defaecation conditions

**Synonym**
Constipation predominant Irritable Bowel Syndrome

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit Maastricht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Abdominal pain, Constipation, Experience Sampling Method, Irritable Bowel Syndrome, Linaclotide

## Outcome measures

### Primary outcome

Primary study outcomes are the proportion of overall responders to linaclotide treatment after 4 and 12 weeks assessed using the ESM-PROM and the conventional end-of-day diary.

### Secondary outcome

Secundary endpoints are symptom scores as reported using the ESM-PROM, concerning abdominal pain, bloating, abdominal fullness, fecal urgency, stool consistency, straining, CSBM frequency and SBM frequency. Additionally, other factors measured using the ESM-PROM, i.e. non-GI physical symptoms, psychological status at the moment of symptom assessment, contextual information regarding the moment of symptom assessment as well as information on food and substance intake.

# Study description

### Background summary

Reliable evaluation of symptoms and their improvement during treatment is crucial in both diagnosing and evaluating response to treatment in IBS. Currently used end-of-day evaluations are considered sub-optimal and the Experience Sampling Method (ESM) was proposed previously as a more accurate symptom assessment method. Aim of this study is to evaluate the responsiveness of the developed ESM-PROM in assessing changes in abdominal pain and stool

frequency after linaclotide treatment of IBS-C patients.

### Study objective

Primary objective of this study is to assess the responsiveness effect size of the ESM-PROM in examining changes in symptom scores between baseline and post-treatment. Secondary objectives are to identify differences in characteristics between responders and non-responders to linaclotide and to assess for side effects of linaclotide treatment, using the ESM-PROM.

### Study design

This is a prospective, observational, single-group, open-label study, initiated and performed in Maastricht University Medical Center (MUMC+).

### Study burden and risks

The burden that is associated with participation in this study comprises completing the ESM-PROM several times a day, which might be time-consuming and possibly interrupts daily life due to its random character. Furthermore, the burden is limited to completing an end-of-day symptom diary and IBS-SSS and GSRS-IBS questionnaire. However, participating does not bring along important risks. A potential disadvantage of study participation is that patients will have to postpone linaclotide treatment with one week (i.e. pre-treatment ESM). However, this is not considered harmful to the patient. No direct benefits are expected, since the study does not contain any interventions. All in all, the risks in this study are considered not disproportional in association with the benefits.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Diagnosis of IBS-C according to Rome IV criteria; negative colonoscopy in the past 5 years prior to inclusion; age between 18 and 75 years; treatment in primary care unsuccessful for 12 months; ability to understand, read and speak the Dutch language; ability to understand how to utilize the MEASuRE app on a smartphone.

## Exclusion criteria

Appendectomy or cholecystectomy within 2 months or other abdominal surgeries within 6 months before entry into the study; history of laxative abuse; current use of drugs that could initiate constipation (e.g. narcotics), use of any IBS-related drugs possibly causing constipation (e.g. tricyclic antidepressants) are a reason for exclusion, unless usage is on a stable dose for at least 30 days before inclusion and there is no plan to change the dose during the study period.

# Study design

## Design

**Study type:** Observational non invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |

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| Primary purpose: | Basic science |

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-02-2018 |
| Enrollment: | 30 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 14-06-2017 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 05-10-2017 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

## 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 |
| --- | --- |
| ClinicalTrials.gov | NCT03336034 |
| CCMO | NL60925.068.17 |