Effectiveness and cost-effectiveness of sacral neuromodulation in patients with idiopathic slow-transit constipation refractory to conservative treatment

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The main objective of this study is assessing the effectiveness of SNM compared to personalized conservative treatment (PCT) in patients with idiopathic slow-transit constipation refractory to conservative treatment. The secondary objectives are…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON50732

Source
ToetsingOnline

Brief title
SNM for constipation

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Constipation, slow-transit constipation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Medtronic B.V.,Zorgkosten worden gefinancierd vanuit het programma voorwaardelijke toelating van Zorginstituut Nederland. Studiekosten worden gefinancierd door Medtronic.

Intervention

Keyword: constipation, cost-effectiveness, effectiveness, SNM

Outcome measures

Primary outcome

The main outcome is treatment success. Patients with an average defecation frequency (DF) of *3 a week are considered successfully treated. Patients with an average DF of <3 a week are considered not successfully treated. This is a clinically relevant outcome, consistent with the internationally widely accepted Rome-IV criteria for idiopathic constipation. DF will be measured using a defecation diary (DD) over a period of 3 weeks (patient-reported).

Secondary outcome

* Proportion of patients with a 50% reduction in the proportion of defecations with straining, derived from the defecation diary.

* Proportion of patients with a 50% reduction in the proportion of defecations with a sense of incomplete evacuation, derived from the defecation diary

* Constipation severity, displayed with the score from the Wexner constipation score (WCS).

* Fatigue, displayed with the score from the *Verkorte vermoeidheidsvragenlijst* (VVV)

* Constipation-specific (health-related) quality of life ((HR)QOL), displayed with the score from the Patient Assessment of Constipation * Quality of Life (PAC-QOL) questionnaire.

* Generic (HR)QOL, measured with the EQ-5D-5L, the ICECAP-A (adults) and the KIDSCREEN-27 (adolescents)

* Adverse events/complications, reported by the clinician in a case report form (CRF)

* Resource use/costs from a societal and health care perspective

* Cost-effectiveness from a societal and health care perspective

* Budget-impact from a societal, health care and health care insurance perspective

Study description

Background summary

Previous reviews showed that the evidence regarding the effectiveness of sacral neuromodulation (SNM) in patients with therapy-resistant, idiopathic (slow-transit) constipation is of suboptimal quality. Furthermore, there is no evidence regarding costs and cost-effectiveness in this patient group.

Study objective

The main objective of this study is assessing the effectiveness of SNM compared to personalized conservative treatment (PCT) in patients with idiopathic slow-transit constipation refractory to conservative treatment. The secondary objectives are assessing the 1) costs, 2) cost-effectiveness and 3) budget-impact of SNM compared to PCT.

Study design

An open-label pragmatic randomized controlled trial (RCT).

Intervention

The intervention is SNM, a minimally invasive surgical procedure consisting of two phases. In the screening phase an electrode is inserted near the third sacral nerve and connected to an external stimulator. If the screening phase is successful (average defecation frequency (DF) *3 a week), the electrode is connected to a pacemaker that is implanted in the buttocks of the patient.

The control intervention is PCT. This is the best and least invasive alternative to SNM. PCT consists of medication and/or retrograde colonic irrigation.

Study burden and risks

Currently, the mechanism of action of SNM is not fully elucidated. However, we believe that this will not pose any extra risk on the subjects. All reported complications of SNM were grade I to grade III complications (i.e. not life-threatening). As PCT is equal to the care that patients received before the start of the study, this control intervention will not pose any additional risks on the participants. All outcomes are measured with questionnaires. Hence, the patient burden of study participation is relatively small.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

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

Inclusion criteria

- An average defecation frequency (DF) of <3 per week based on a 3-week defecation diary (patient-reported)
- Meet at least one other criterion of the Rome-IV criteria for idiopathic constipation based on the 3-week defecation diary
- Resistant to conservative treatment (i.e. an average DF of <3 per week and meet at least one other criterion of the Rome-IV criteria despite maximal conservative treatment. This means that the patient must have been resistant to the following treatments: lifestyle changes, laxatives, enemas and retrograde colonic irrigation)
- Age: 14-80 years
- Slow-transit constipation

Exclusion criteria

* Obstructed outlet syndrome (objectified by defeacography)
* Irritable bowel syndrome (Rome-IV criteria for irritable bowel syndrome)
* Congenital or organic bowel pathology
* Rectal prolapse
* Anatomical limitations preventing placement of an electrode
* Skin and perineal disease with risk of infection
* Previous large bowel/rectal surgery
* Stoma
* Coexisting neurological disease
* Significant psychological co-morbidity as assessed subjectively by the investigator
* Being or attempting to become pregnant during study follow-up

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2017
Enrollment:	67
Type:	Actual

Medical products/devices used

Generic name:	sacral neuromodulation
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	15-06-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-12-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-09-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-06-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

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	NCT02961582
CCMO	NL57367.068.16