“The "I-aid": A new care pathway to improve quality of care and quality of life in ileostomy and colostomy patients”.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21143

Source
NTR

Brief title
I-aid trial

Health condition

Attachment, Ileostomy, colostomy, Leakage, Feces, Skin irritation, stoma care, stomacare nurse, stoma related morbidity, costs

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

1. The percentage of patients with one or more stoma-related complications occurring within three months after receiving the ostomy. This time interval is chosen because within this

period the stoma reaches its final shape and the vast majority of complications occurs. Stoma-related complications are: peristomal leakage, skin irritation, stomal dehiscence, retraction, protrusion, or stenosis, infection, and hemorrhage, according to standard predefined criteria;

2. Patients' quality of life, measured by means of the validated Stoma-Qol questionnaire (Prieto 2005), consisting of 20 items scored on a 4-point scale, and the EQ-5D to enable calculation of QALYs. These parameters will be assessed before surgery and 1 and 3 months after receiving the stoma.

Secondary outcome

Number and costs during the follow-up period of used stoma materials, outpatient visits, readmissions, the personnel involved, as well as the out-of-pocket expenses by patients.

Study description

Background summary

"The "I-aid": a new care pathway to improve quality of care and quality of life in ileostomy and colostomy patients"

Objective:

To provide evidence whether a new perioperative care pathway for patients requiring an ileo- or colostomy reduces complication rates and improves quality of life against acceptable costs. Previous national surveys among ostomates and stoma care nurses have shown variation in care. Literature shows the incidence of stoma-related complications is high, indicating room for improvement. Our recent pilot study indicated that additional postoperative home visits by stoma care nurses help improve stoma care and avoid complications. Hence, a care pathway comprising careful perioperative instruction and postoperative follow-up may provide a better quality of care for these patients.

Study design:

Fifteen-centre cluster randomised clinical study with a stepped wedge design, so that at the end of the study all centres will have adopted the new care pathway.

Study population:

Patients receiving an ileostomy or colostomy for any inflammatory or malignant distal bowel disorders or a trauma.

Intervention:

Current perioperative ostomy care vs. a new pre- and postoperative ostomy care pathway ("I-aid") including home visits.

Outcome measures:

Stoma-related complications within 3 months after the ostomy has been placed, stoma-related quality of life, number of readmissions, number and costs of consumables used for stoma care, number of outpatient and home visits and personnel involved within the follow-up period.

Sample size calculation / data analysis:

A total of 210 patients are needed to detect a 50% reduction in stoma-related complication rate (from 50% to 25%) with a power of 80% and at a one-sided alpha of 0.05.

Economic evaluation:

From a societal perspective, the costs per stoma-related complication and costs per quality adjusted life year will be calculated and compared between the two care groups, with a time horizon of 3 months.

Time schedule:

Two months of study preparation, 18-month inclusion period, 3 months of follow-up and 1 month to finalise data-analysis and reporting; this totals 24 months.

Study objective

To provide evidence whether a new perioperative care pathway for patients requiring an ileo- or colostomy reduces complication rates and improves quality of life against acceptable

costs.

Study design

Stoma-related complications occurring within three months after receiving the stoma will be recorded during the outpatient or home visits. This will yield the percentages of patients with a stoma-related complication in both intervention groups.

In addition, patients will be asked to complete the EQ-5D at baseline and the StomaQol after one and three months of follow-up, to generate health status scoring profiles over time, which will subsequently be transposed into health utilities using population based tariffs of time trade-off ratings of health states. The internationally most frequently applied UK tariffs will be used for the main analysis (Dolan 1997), with the impact of alternative, Dutch tariffs (Lamers 2005) assessed by sensitivity analysis. Based on the health utility scores over time, QALYs will be calculated by taking the product sum of the health utility scores and the periods in-between successive measurements during the three months of follow-up.

Intervention

We intend to investigate the costs and effectiveness of a new, uniform ostomy care pathway (the “I-aid”) to improve the quality of care and quality of life of patients who will receive an ostomy. The project covers the investigation of a more elaborate instruction and closer monitoring programme in the perioperative and outpatient phases, particularly by the stoma care nurses.
Present-day care fails in terms of a large variation in care for these ileostomy patients, while the possession of such a stoma is cumbersome, may induce a serious physical and psychological burden, and may lead to serious stoma-related complications, most of which are preventable or can be limited by proper instruction, surveillance and timely action.

Hence, the aim of this project is to investigate whether and to which extent the proposed new care pathway will lead to a reduction in the number of stoma-related complications and a better quality of life at acceptable costs, as compared with the standard perioperative care for ostomate patients.

Implementing a different care pathway:

Individual contributing centres will be clustered in three and, subsequently, randomly assigned to five different wedges that will receive the I-aid care pathway according to a sequential rollout over a number of time periods (see flowchart). Each cluster of three hospitals will start with the standard peri-operative care protocol during a period of three months. After three months, three of the fifteen centres will be selected randomly to start with the I-aid care pathway and continue to do so for the remainder of the study. This will be repeated each time a new quarter begins. The patients cannot choose between the different kinds of pathways. During the sixth quarter the final three centres will start to introduce the I-

aid care pathway, so that by the end of the study, all hospitals will have adopted the I-aid care pathway. The study will follow the validity criteria as described by Fan et al. (Fan 2010).

The standard peri-operative pathway:

In short, the standard peri-operative care protocol, as defined by the stoma working group, prescribes the following actions:

Four to six weeks before the operation the patient will visit the outpatients clinic of the stomatherapist: to inform the patient and his relatives about the surgical procedure, the anticipated stoma and its consequences. Quality of life questionnaire (EQ-5D) will be asked to fill in. Also the patient will be asked to fill in a stoma care diary during the first three months after surgery.
Two weeks after the operation the patient will visit the outpatients clinic of the stomatherapist and the surgeon.

One and three month there will also be a visit at the outpatient clinic of the stomatherapist. The patients have to fill in another quality of life questionnaire (stomaqol).

The I-aid peri-operative care pathway:

The stomatherapists will visit the patient pre-operative, one month and three months at home. The Quality of life questionnaires and the stoma care diary will be asked to fill in at the same time.

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Eligibility criteria

Inclusion criteria

1. All patients who receive a planned end or loop colo- or ileostomy;

2. Age between 18 and 85 years;

3. Written informed consent.

Exclusion criteria

1. Life expectancy of less than one year;

2. BMI > 35 or < 18;

3. Emergency surgery;

4. ASA IV;

5. Insufficient command of the Dutch language or cognitively unable to complete Dutch questionnaires;

6. Dementia.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2012
Enrollment:	210
Type:	Anticipated

Ethics review

Positive opinion Date:	05-03-2012
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	NL3132
NTR-old	NTR3332
Other	METC AMC : 2011_370
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A