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

Published: 27-03-2012
Last updated: 30-04-2024

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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON37501

Source
ToetsingOnline

Brief title
I-aid trial

Condition

- Gastrointestinal therapeutic procedures

Synonym
stoma: artificial exit of the intestinal tract in the abdomen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: care pathway, complications, ostomy, quality of life

Outcome measures

Primary outcome

Outcome measures: Stoma-related complications within 3 months after the ostomy has been placed.

Secondary outcome

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.

Study description

Background summary

In patients with inflammatory or malignant bowel diseases an ileostomy or colostomy is a frequently applied intervention for example to deviate faecal flow to the abdominal wall to allow for recovery of the more distal, diseased or operated, parts of the bowel. In the Netherlands, over 2000 patients (UK: 9000) yearly receive an ileostomy for various inflammatory or malignant bowel disorders. Although this stoma is meant to be temporary, it usually remains in situ for months and may even become permanent in some patients.
From both national and international publications we know that having a stoma seriously impacts patients' daily functioning (Bakx 2004, Redmond 2009). The reported percentage of patients suffering from a stoma-related complication ranges from 19 to 70% (Ratcliff 2010, Giannakopoulis 2009, Bakx 2004). Possible complications are peristomal leakage, skin irritation, stomal dehiscence, retraction, protrusion, or stenosis, infection, and hemorrhage (Cottam 2007, Kaidar-Person 2005, Bell 2005, Hallböök 2002, Park 1999, Gooszen 1998). About 40% of these complications occurs already within one month after receiving the stoma. Risk factors for the occurrence of stoma-related complications are obesity, inflammatory bowel diseases (Duchesne2002).
The care given by stoma care nurses may avoid complications (odds ratio 0.15, 95% confidence interval 0.03 * 0.69) (Duchesne 2002).
Three-quarters of the Dutch patients with an ostomy report having a stoma is a

serious limitation on the social, sexual, and physical levels (Bekkers 2004). About half of these patients have had a stoma-related complication. One quarter of them complains about a lack of knowledge, skills and education by the caregivers. The inadequate communication is amplified by the current trend towards shortening of the hospital stay. Finally, costs are an important aspect, not only to healthcare but also to
the patient, in terms of out-of-pocket expenses (e.g. specific clothing, extra cleaning and bed-linen).
Thus, this project may lead to substantial benefits, but at additional costs of home visits by stoma care nurses. This can be worthwhile as these patients deserve careful perioperative instruction and transmural follow-up to ensure the best possible quality of care and quality of life.

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. 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.

Intervention

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

Study burden and risks

The patient will be asked to fill in a couple of questionnaires, to keep a diary.
Patients will be visited at home by the stomatherapist.
There are no extra risks involved.

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

- All patients who receive a planned end or loop colo- or ileostomy
- Age between 18 and 85 years
- Written informed consent

Exclusion criteria

Life expectancy of less than one year
- BMI > 35 or < 18
- Emergency surgery
- ASA-category IV
- Insufficient command of the Dutch language or cognitively unable to complete Dutch

questionnaires.
- Demention

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2013
Enrollment:	210
Type:	Actual

Ethics review

Approved WMO Date:	27-03-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-07-2012
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-09-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL39077.018.11