Intracutaneously versus transcutaneously sutured ileostomy: A randomized multicenter trial (ISI trial).

No registrations found.

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

Summary

ID

NL-OMON23654

Source
NTR

Brief title
ISI trial

Health condition

patients requiring an ileostomy for malignant or infectious diseases of the intestinal tract.

ileostomy, leakage, feces, skin irritation, stitches, sutures

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: dansac, coloplast, convatec

Intervention

Outcome measures

Primary outcome

Leakage of feces under the stoma plaque and peristomal dermatitis around the stitches or

due to leakage of feces.

Secondary outcome

1. Quality of life, as measured by the Stoma-Qol;

2. Stoma-related morbidity;

3. Cost analysis (Stoma materials and outpatient visits).

Study description

Background summary

In colorectal surgery, an ileostomy is often constructed to protect temporarily a distal colonic anastomosis. Even though the construction of an ileostomy is a procedure commonly performed by both general and colorectal surgeons, it has a high morbidity rate. In several studies the complication rate varied between 21 and 60 per cent. Thus, receiving an ileostomy has been associated with a decreased quality of life and a reduced physical and psycological well being.

Enterostomal therapists see many stoma-related complications, for example leakage of feces under the stoma plaque. This in turn can cause peristomal dermatitis, granuloma and fungal infections.

The objective of this trial is to compare the effectiveness of intracutaneously versus transcutaneously sutured ileostomy to reduce leakage, costs and to improve patients'quality of life. The transcutaneous character of the stitches can cause skin irritation around the stitches, it might cause leakage of feces under the stoma plaque thereby increasing skin irritation and early release of stoma plaque. This will also increase costs, because the stoma materials will have to be changed more often.

The trial is designed as a 10-center randomized clinical trial including all patients who receive an ileostomy. Patients will be randomized to receive either an intracutaneously or transcutaneously sutured ileostomy. Primary outcomes are leakage, skin irritation, costs and the patients' quality of life.

In order to detect an effect size of 0.05 at a 5% two-sided significance level with a power of 80%, a minimum sample size of 134 patients per treatment group is required. Patients will be included from September 2010 until March 2012, with a minimum follow-up duration of three months.

Study objective

An intracutaneously sutured ileostomy may be more effective than a transcutaneously sutured ileostomy to reduce peristomal dermatitis, leakage and costs and to improve quality of life of patients with an ileostomy.

Study design

1. Skin irritation and stoma related morbidity: At one week, two weeks, one month, two and three months;

2. !uality of life: One month and three months;

3. Cost analysis with a diary up to three months.

Intervention

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Contacts

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Eligibility criteria

Inclusion criteria

1. All patients who receive an end or loop ileostomy;

2. Age between 18 and 80 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-09-2010
Enrollment:	268
Type:	Anticipated

Ethics review

Positive opinion Date:	09-06-2010
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	NL2243
NTR-old	NTR2369
Other	METC AMC : 10/150
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A