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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23654

Bron
Nationaal Trial Register

Verkorte titel
ISI trial

Aandoening

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

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

Ondersteuning

Primaire sponsor: AMC
Overige ondersteuning: dansac, coloplast, convatec

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Leakage of feces under the stoma plaque and peristomal dermatitis around the stitches or due to leakage of feces.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

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Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

2. Age between 18 and 80 years;

3. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2010
Aantal proefpersonen:	268
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-06-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2243
NTR-old	NTR2369
Ander register	METC AMC : 10/150
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A