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

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In this trial we will compare two ways of suturing the ileostomy, intracutaneous sutures or transcutaneous sutures (hence the acronym ISI-trial; Intracutaneously Stitched Ileostomy trial). There is no consensus about which technique should be used....

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Epidermal and dermal conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON34429

**Source**
ToetsingOnline

**Brief title**
ISI trial

### Condition

- Epidermal and dermal conditions
- Lifestyle issues
- Gastrointestinal therapeutic procedures

**Synonym**
artificial opening of the small intestine, ileostomy

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:**
Coloplast,Convatec,Dansac,Dansac;Convatec;Coloplast

## Intervention

**Keyword:** costs and quality of life, Ileostomy, stoma leakage, stoma-related complications

## Outcome measures

### Primary outcome

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

stitiches or due to leakage of feces

### Secondary outcome

Quality of life, as measured by the Stoma-QoI

Stoma-related morbidity

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 ileostomy construction is a common procedure performed by both general and colorectal surgeons, it has a high morbidity rate. In several studies the complication rate varies between 21 and 60 per cent. As a result of these complications the costs of management of a complicated stoma are high. Thus, receiving an ileostomy is associated with a decreased quality of life, physical and psychological well-being.
In the Netherlands it is unclear how many ileostomies are created yearly. We estimate that there are 2000 new patients each year, while in the UK there are as many as 9000 new ileostomies each year.
Obviously the patient who will receive an ileostomy has to be informed about living with such a stoma. Nowadays an enterostomy nurse is active in many hospitals. They counsel patients and surgeons to determine the proper location of the stoma and teach the patient how to properly care for the stoma. Through the careful follow-up by the enterostomy nurse many of the stoma-related complications are now recognized and, if possible, dealt with appropriately.
It is important to select the optimal site for the formation of the stoma

before the operation takes place. The position for the stoma is marked with the patient standing, bending and sitting so to make sure that the stoma is not in a skin crease and that it is visible to the patient in all positions. An inappropriate site leads to leakage, skin irritation, and skin break down around the stoma.
Ileostomies produce watery and frequent stool, especially in the early postoperative phase. The proteolytic enzymes and high alkaline content of the stool can damage the epidermal structure. This is responsible for the increased incidence of skin irritation. Peristomal dermatitis is a large problem for ileostomy patients. 65% of the patients with an ileostomy have reported to have peristomal dermatitis. One of the factors that cause peristomal dermatitis is leakage of feces under the stomaplaque. Causes for leakage of feces are an inappropriate site, wrong use of stoma material, retraction or a parastomal hernia. Leakage of feces under the stoma plaque will require changing the stoma plaque more often. This will cause extra damage to the peristomal skin.
Generally, surgeons fixate ileostomies to the skin my means of transcutaneous stitches. There are, however, no solid data on how to create a stoma and what kind of suture technique should be used. It can be hypothesized that the transcutaneous character of the stitches allows feces to penetrate under the stomaplaque and thereby increase skin irritation and early release of the stomaplaque. Hence,it will increase costs because more stoma materials are needed. Stitching the ileostomy intracutaneously instead of transcutaneously may reduce the leakage of feces under the stoma plaque.

### Study objective

In this trial we will compare two ways of suturing the ileostomy, intracutaneous sutures or transcutaneous sutures (hence the acronym ISI-trial; Intracutaneously Stitched Ileostomy trial). There is no consensus about which technique should be used. A frequently occurring stoma-related complication is leakage of feces under the stomaplaque that can cause peristomal dermatitis. This also causes early release of the stomaplaque, so this has to be changed more often. The hypothesis is that the transcutaneous character of the stitches give irritation of the skin and more readily allows feces to appear under the stoma plaque and thereby increases skin irritation and early release of stoma plaque. This will increase costs because more stoma material needs to be used.

### Study design

Randomized single-blind multicenter trial.

### Intervention

Stitching the ileostomy intracutaneously instead of transcutaneously

### Study burden and risks

The patient will be asked to fill in a couple of questionnaires, to keep a diary and to visit the outpatients clinic.
The risks are mild en exit of only very rare (allergic) reactions on the used suture material.

## 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 an end or loop ileostomy
- Age between 18 and 80 years
- Written informed consent

### Exclusion criteria

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

## Study design

### Design

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-04-2011 |
| Enrollment: | 300 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Application type: | First submission |
| 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 | NL32731.018.10 |