

# Traditional lateral ileostomy vs percutaneous ileostomy by exclusion probe for the protection of the extraperitoneal colo-rectal anastomosis (Ileostomia laterale tradizionale vs ileostomia percutanea escludente su sonda dedicata a protezione della anastomosi colorettali extraperitoneali)

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>19/02/2012   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>02/05/2012 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>20/04/2017       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

### Background and study aims

Rectal cancer is cancer of the back passage (rectum). Surgery to treat rectal cancer involves the resection (removal) of the rectum and attachment of the colon to the remainder of the rectum (colorectal anastomosis). A conventional ileostomy is usually performed, where the small intestine is diverted through an opening in the abdomen (stoma), which requires a second operation to be closed. The aim of this study is to assess the effectiveness and safety of percutaneous ileostomy by probe, where a tube is inserted into the small intestine which can be removed without a second operation.

### Who can participate?

Patients aged over 18 with rectal cancer undergoing surgery

### What does the study involve?

Participants are randomly allocated to undergo either conventional ileostomy or percutaneous ileostomy by probe. Anastomotic leakages and complications due to the placement and removal of the probe are assessed.

### What are the possible benefits and risks of participating?

Percutaneous ileostomy by probe may be more comfortable than conventional ileostomy and doesn't require another operation to be removed. The risk is that percutaneous ileostomy by probe leads to anastomotic leakages and peritonitis (inflammation of the lining of the abdomen).

Where is the study run from?  
Ospedale San Giovanni Battista (Italy)

When is the study starting and how long is it expected to run for?  
February 2012 to December 2015

Who is funding the study?  
Umbria Local Health Office No.3 (Italy)

Who is the main contact?  
Dr Enrico Mariani  
enrico.mariani@yahoo.it

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
RO-MA 01 N.28657/1/AV

## Study information

**Scientific Title**  
Traditional lateral ileostomy vs percutaneous ileostomy by exclusion probe for the protection of the extraperitoneal colo-rectal anastomosis (Ileostomia laterale tradizionale vs ileostomia percutanea escludente su sonda dedicata a protezione della anastomosi colorettali extraperitoneali): the ALPPI (Anastomotic Leak Prevention by Probe Ileostomy) trial

**Acronym**  
ALPPI

**Study objectives**

Percutaneous ileostomy is safe and effective in protecting low colo-rectal anastomosis as lateral conventional ileostomy, and it is well tolerated and it doesn't need another surgical procedure for the closure.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics Committee of Regional Public Health System of Umbria, 15/09/2011, Protocol Number 28657/11/AV

**Primary study design**

Interventional

**Study design**

Multicentre open randomized parallel-group study

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Colorectal cancer

**Interventions**

The comparison of two different ileostomy: conventional lateral ileostomy vs percutaneous ileostomy by probe

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

The protection of the extraperitoneal colo-rectal anastomosis in term of asymptomatic or symptomatic leakage

**Key secondary outcome(s)**

1. The evaluation of any local complications due to the probe removal
2. Short and long-term general complications

**Completion date**

31/12/2015

**Eligibility****Key inclusion criteria**

1. Age  $\geq$  18 years
2. Elective surgery (prepared colon or rectum)
3. Neoplastic disease of the colon-rectum
4. Approved informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**Key exclusion criteria**

1. Age < 18 years
2. Emergency surgery (prepared colon or rectum)
3. Pregnancy or breastfeeding in course
4. Indications for another type of surgery different from the neoplastic disease
5. Inflammatory bowel diseases
6. Refusal to provide informed consent

**Date of first enrolment**

20/02/2012

**Date of final enrolment**

31/12/2015

**Locations****Countries of recruitment**

Italy

**Study participating centre**

Ospedale San Giovanni Battista

Foligno

Italy

06034

**Sponsor information****Organisation**

Umbria Local Health Office No.3 (Azienda Sanitaria Locale N. 3 dell Umbria) (Italy)

# Funder(s)

## Funder type

Government

## Funder Name

Umbria Local Health Office No.3 (Azienda Sanitaria Locale N.3, Umbria) (Italy)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/04/2014   |            | Yes            | No              |