# 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)

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>		
19/02/2012		☐ Protocol		
Registration date 02/05/2012	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
20/04/2017	Cancer			

## 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

Dr Enrico Mariani

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers** 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 Commitee of Regional Public Health System of Umbria, 15/09/2011, Protocol Number 28657/11/AV

#### Study design

Multicentre open randomized parallel-group study

#### Primary study design

Interventional

#### Secondary study design

Randomised parallel trial

#### Study setting(s)

Hospital

## Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

## 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 measure

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

#### Secondary outcome measures

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

#### Overall study start date

20/02/2012

#### Completion date

31/12/2015

# **Eligibility**

#### Key inclusion criteria

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

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

# Target number of participants

200 (100 per arm)

#### 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

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)

#### Sponsor details

Piazza Giacomini, 40 Foligno (Perugia) Italy 06034 +39 (0)7 423 391 enrico.mariani@yahoo.it

## Sponsor type

Government

#### Website

http://www.asl3.umbria.it

# Funder(s)

## Funder type

Government

#### **Funder Name**

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

# **Results and Publications**

## Publication and dissemination plan

Not provided at time of registration

# Intention to publish date

# 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?
Results article	results	01/04/2014		Yes	No