

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 coloretali extraperitoneali)

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

Study design

Multicentre open randomized parallel-group study

Primary study design

Interventional

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?
Results article	results	01/04/2014		Yes	No