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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
19/02/2012

Recruitment status
No longer recruiting

Registration date
02/05/2012

Overall study status
Completed

Last Edited
20/04/2017

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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

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)

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Sponsor type
Government

Website
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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