Prevention of septic complications in low anterior resection for rectal carcinoma: the role of Platelet Derived Growth Factors. A pilot study

Published: 25-03-2013
Last updated: 26-04-2024

To investigate the feasibility of using L-PRP on anastomosis to prevent septic complications from occuring.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Anal and rectal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON39406

Source
ToetsingOnline

Brief title
Prevention of septic complications in low anterior resection

Condition

- Anal and rectal conditions NEC

Synonym
rectal cancer / anastomotic leakage

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Het onderzoek zal niet worden gefinancierd.

BIOMET heeft geen enkele invloed op de inhoud van het protocol en de studie.

Intervention

Keyword: complication, growth factors, low anterior resection, rectal carcinoma

Outcome measures

Primary outcome

The occurrence of septic complications; anastomotic leak, presacral

abscess/sinus, perineal wound problems.

Secondary outcome

- Registration of other complications

- Cost-effectiveness analysis

Study description

Background summary

In Holland there is an increasing incidence of rectal cancer. Surgical treatment of rectal cancer is a total mesorectal excision (TME). Within the TME, an abdominoperineal resection (APR) of a low anterior resection (LAR) can be performed. Concerning LAR, the continuity of the colon is restored by establishing a low anastomosis. The most important problems after LAR are septic complications as anastomotic leakage, abdominal or pelvic abscesses, wound infections and and persisting presacral sinus.
The incidence of septic complications after LAR varies between 10 and 20 percent. Anastomotic leakage occurs in around 10 percent of the cases and goes hand in hand with significant morbidity and mortality. The mortality rate for an anastomotic leak is around 30 percent. To this day a proper solution for the prevention of septic complications after LAR for rectal cancer still remains to be found.
Promising results have been published concerning the role of Leucocytes - Platelet Rich Plasma (L-PRP) in the process of wound healing. Our hypothesis is that this will also be the case in the healing of the low anastomosis after low anterior resection, and thus that L-PRP will help to prevent septic complications from occuring in these patients.

Study objective

To investigate the feasibility of using L-PRP on anastomosis to prevent septic complications from occuring.

Study design

Pilot study

Intervention

- The application of L-PRP in a single dose, applied onto the anastomosis

Study burden and risks

All patients will undergo the standardized low anterior resection with omentoplasty. In all patients, a single dose of L-PRP will be applied onto the anastomosis which has no additional risks. All patients will get the standard follow-up after low anterior resection.

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

Patients eligible for undergoing a low anterior resection

Exclusion criteria

Patients who are physically incapable of undergoing invasive surgery like low anterior resection

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO

Date:	25-03-2013
Application type:	First submission

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

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	NL40558.096.12