

transanal total rectal excision a hybrid notes procedure the introduction of a new technique

Published: 06-06-2012

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The objective of this new approach is: to reduce the number of conversionsfaster
recoveryshorter hospital stay

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON37580

Source

ToetsingOnline

Brief title

transanal TME

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym

bowel cancer laparoscopic surgery

Research involving

Human

Sponsors and support

Primary sponsor: Ziekenhuisvoorzieningen Gelderse Vallei

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: NOTES, rectal carcinoma, single port

Outcome measures

Primary outcome

-

Secondary outcome

-

Study description

Background summary

the standard treatment of rectal cancer is currently a laparoscopic low anterior resection. unfortunately this technique is not always possible and in about 20% of the laparoscopic operations have to be converted to a classic open technique. This is mostly in patient's with little space in the pelvis and thereby not enough space to dissect around the tumor. the consequences of a conversion are an increased hospital stay and more wound related complications.

the objective is to introduce a technique which reduces the number of conversions.

in this new technique the rectum is mobilised transrectally

Study objective

The objective of this new approach is:
to reduce the number of conversions
faster recovery
shorter hospital stay

Study design

a feasibility study to introduce the new technique

Study burden and risks

no

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

rectal cancer (RT at least 6cm from dentate linea)
T2-T3 tumors (MRI)
no previous abdominal surgery
age 18-75

Exclusion criteria

previous transrectal sugery

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2012
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO	
Date:	06-06-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL39355.029.12