



## Trial Description

### Title

**clinical Outcome and Quality of Life of patients after low anterior resection (and total mesorectal excision if Cancer is locally spreaded) with NiTi-Colonring**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**In this study the newer Anastomosisdevice "NiTi-Colonring" (NiTi-Surgical) shall be examined und analysed.**

**Patient suffering under Rectal-Cancer will be examined and asked about complications and their Quality of Life befor and after the operation.**

**Afterwards there will be a comparison between datas (already existing) of patients whose anastomosis is done with a "normal" device.**

**We want to show, that, at this operation (low anterior resection), the clinical Outcome of the Patient ist not worse than with older devices.**

### Brief Summary in Scientific Language

**Analysis of the clinical outcome of Patients with Rectal-Cancer, anastomosis done with NiTi-Colonring (clinical examination). Questionnaire about Quality of Life before the first operation and before shift back of the Ileostoma.**

**To Show: non-inferior of the Colonring**

## Organizational Data

- DRKS-ID: **DRKS00003108**
- Date of Registration in DRKS: **2011/05/25**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2011-247N-MA , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **C20 - Malignant neoplasm of rectum**

## Interventions/Observational Groups

- Arm 1: **monitoring group: patients with low anterior resection, Anastomosis with NiTi-Colonring.**

**Questionnaires about Quality of Life from the EORTC (European Organisation for Research and Treatment of Cancer)**  
**Moduls: QLQ C30, Cr29**

**Time of questioning: directly before the first operation (low anterior resection with anastomosis) and directly before the shift back of the ileostoma**

- Arm 2: **historical reference group: Datas of the database of the surgical section of the university medical centre about Patients with low anterior resection, anastomosis done with normal staple-device**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Other**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]\*
- Control: **Historical**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]\*

### Primary Outcome

**Anastomosisinsufficiency during a 3month period of surveillance**

### Secondary Outcome

**time till bowel and bladder work again, first tolerated food (both liquid and solid), equipment malfunctions during operation, bleeding, stricture, septical complication,**

**and recurrence of Cancer, re-operation oder death within 30days after operation,  
Quality of Life (EORTC QLQ C30, CR29)**

## Countries of recruitment

- **DE Germany**

## Locations of Recruitment

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/06/01**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**Rectal-Resection (with or without total mesorectal excision) and anastomosis done with NiTi-Colonring**

### Exclusion criteria

**Patient younger than 18 years**

## Addresses

- **Primary Sponsor**  
**Chirurgische Klinik Mannheim**  
**Theodor-Kutzer-Ufer 1-3**

### **Primary Sponsor**

**Chirurgische Klinik Mannheim  
Theodor-Kutzer-Ufer 1-3  
68167 Mannheim  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

### ■ **Contact for Scientific Queries**

**Chirurgische Klinik Universitätsmedizin Mannheim  
Mr. Prof. Dr. med Peter Kienle  
Theodor-Kutzer-Ufer 1-3  
68167 Mannheim  
Germany**

Telephone: **0621 / 383 2225**

Fax: **0621 / 383 3809**

E-mail: **peter.kienle at umm.de**

URL: [---]\*

### ■ **Contact for Public Queries**

**Chirurgische Klinik Universitätsmedizin Mannheim  
Mr. Prof. Dr. med Peter Kienle  
Theodor-Kutzer-Ufer 1-3  
68167 Mannheim  
Germany**

Telephone: **0621 / 383 2225**

Fax: **0621 / 383 3809**

E-mail: **peter.kienle at umm.de**

URL: [---]\*

## **Sources of Monetary or Material Support**

### ■ **Institutional budget, no external funding (budget of sponsor/PI)**

**Chirurgische Klinik, Universitätsmedizin Mannheim  
Theodor-Kutzer-Ufer 1-3  
68167 Mannheim  
Germany**

Telephone: [---]\*

Fax: [---]\*



---

**Institutional budget, no external funding (budget of sponsor/PI)**

**Chirurgische Klinik, Universitätsmedizin Mannheim**

**Theodor-Kutzer-Ufer 1-3**

**68167 Mannheim**

**Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

## Status

- Recruitment Status: **Recruiting stopped after recruiting started**
- Study Closing (LPLV): [---]\*

## Trial Publications, Results and other documents

\* This entry means the parameter is not applicable or has not been set.

\*\*\* This entry means that data is not displayed due to insufficient data privacy clearing.