# Joint neuromonitoring project: Continuous intraoperative neuromonitoring as a microtechnological navigation instrument for surgical procedures with subproject of medical and scientific investigations in the minor pelvis

Submission date 04/03/2010	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 09/04/2010	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 09/04/2010	<b>Condition category</b> Surgery	<ul> <li>Individual participant data</li> <li>Record updated in last year</li> </ul>

**Plain English summary of protocol** Not provided at time of registration

## **Contact information**

**Type(s)** Scientific

**Contact name** Dr Werner Kneist

### Contact details

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## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

### ClinicalTrials.gov number

Secondary identifying numbers 01EZ0726

## Study information

#### Scientific Title

Joint neuromonitoring project: Continuous intraoperative neuromonitoring as a microtechnological navigation instrument for surgical procedures with subproject of medical and scientific investigations in the minor pelvis: An open label, prospective, controlled trial

#### Acronym

IKONA

#### **Study objectives**

Intermittent and continuous intraoperative monitoring of pelvic autonomic nerves during nerve-sparing mesorectal excision minimisess postoperative complications such as urogenital and anorectal dysfunction.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Local ethics committee (Ethik-Kommission der Landesärztekammer Rheinland-Pfalz) approved on the 14th October 2009 (ref: 837.473.08 [6470])

**Study design** Open controlled prospective clinical single centre study

**Primary study design** Interventional

Secondary study design Non randomised controlled trial

Study setting(s) Hospital

**Study type(s)** Other

#### Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Intraoperative nerve monitoring

#### Interventions

Experimental intervention:

Nerve-sparing mesorectal excision with both intermittent and continuous intraoperative monitoring of pelvic autonomic nerves in patients with rectal cancer. Prospective evaluation of urogenital and anorectal function postoperatively. The inferior hypogastric plexus and pelvic splanchnic nerves are identified and electrodes are placed to ensure the continuous subliminal application of electricity. The stimulation response is assessed based on electromyogram (EMG) signals from the internal anal sphincter and manometry of the urinary bladder.

Duration of intervention per patient:

Neuromonitoring is associated with an expected extension in operative time of approximately 20 to 40 minutes. The total duration of follow up will be approximately 3 weeks.

### Intervention Type

Procedure/Surgery

### Phase

Not Specified

### Primary outcome measure

Examination of functionality of continuous intraoperative monitoring of pelvic autonomic nerves during nerve-sparing mesorectal excision in rectal cancer patients

### Secondary outcome measures

1. Examination of functionality of selective identification and intermittent intraoperative monitoring of pelvic autonomic nerves during nerve-sparing mesorectal excision in rectal cancer patients

- 2. Comparison of neurostimulation results with the observed clinical data
- 2.1. Preoperative data:
- 2.1.1. Anamnesis
- 2.1.2. Indication for operation
- 2.1.3. Clinical staging
- 2.1.4. Standardised questionnaires:
- 2.1.4.1. International Prostate Symptom Score (IPSS)
- 2.1.4.2. Quality of Life (QoL)
- 2.1.4.3. Cleveland Clinic Incontinence Score (CCIS)
- 2.1.4.4. Memorial Sloan-Kettering Cancer Center (MSKCC) assessment for anal continence
- 2.1.4.5. International Index of Erectile Function (IIEF)
- 2.1.4.6. Female Sexual Function Index (FSFI)
- 2.1.5. Sonographic assessment of the residual volume
- 2.2. Intraoperative data:
- 2.2.1. Macroscopic assessment of pelvic autonomic nerve preservation
- 2.2.2. Intraoperative complications
- 2.2.3. Assessment of stimulation probes
- 2.3. Postoperative data:
- 2.3.1. Pathological staging
- 2.3.2. Standardised questionnaires (IPSS, Qol, CCIS, MSKCC, IIEF, FSFI)
- 2.3.3. Date of removal of suprapubic or indwelling catheter
- 2.3.4. Need for recatheterisation
- 2.3.5. Sonographic assessment of the residual volume
- 2.3.6. Postoperative complications

### Overall study start date

01/03/2010

### Completion date

01/03/2011

## Eligibility

### Key inclusion criteria

1. Histologically confirmed carcinoma of the rectum

2. Curative or palliative rectal resection, abdomino-perineal rectal extirpation, multivisceral resection

3. Male or female, aged greater than or equal to 18 years

4. Signed declaration of consent

**Participant type(s)** Patient

Age group

Adult

### Lower age limit

18 Years

Sex Both

### Target number of participants

35 participants

### Key exclusion criteria

- 1. Emergency operation
- 2. Transanal Endoscopic Microsurgery (TEM)
- 3. Pacemaker
- 4. General contraindications for operation
- 5. Missing data on urogenital and anorectal function
- 6. Pregnancy and breastfeeding

### Date of first enrolment

01/03/2010

### Date of final enrolment

01/03/2011

## Locations

#### **Countries of recruitment** Germany

**Study participating centre University Medical Centre of the Johannes Gutenberg University Mainz** Mainz Germany 55131

## Sponsor information

**Organisation** University Medical Centre of the Johannes Gutenberg University Mainz (Germany)

**Sponsor details** Department of General and Abdominal Surgery Langenbeckstr. 1 Mainz Germany 55131

**Sponsor type** Hospital/treatment centre

Website http://www.uni-mainz.de/eng/

ROR https://ror.org/00q1fsf04

## Funder(s)

**Funder type** Government

**Funder Name** German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany)

## **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