

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 minimises 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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration