ISRCTN06042867 https://doi.org/10.1186/ISRCTN06042867

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

Contact name
Dr Werner Kneist

Contact details
University Medical Centre of the Johannes Gutenberg University Mainz
Department of General and Abdominal Surgery
Langenbeckstr.1
Mainz
Germany
55131
+49 (0)6131 17 7291
kneist@ach.klinik.uni-mainz.de

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