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Nerve monitoring during robotic radical prostatectomy

Submission date	Recruitment status	[X] Prospectively registered
11/01/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/01/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/02/2013	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Treatment of prostate cancer commonly involves an operation to remove the prostate (a radical prostatectomy) in either open, laparoscopic, or robot-assisted procedures. Erectile dysfunction is a possible side-effect for patients after having a radical prostatectomy. This is because the nerves that are responsible for controlling erectile function can be injured during the surgery. The investigators of this study want to find out if a nerve monitoring device is able to monitor the nerves surrounding the prostate, which are responsible for controlling erectile function.

Who can participate?
Adult males between 18 and 75 years of age who are undergoing robotic radical prostatectomy with no history of significant erectile dysfunction will be asked to participate.

What does the study involve?
All eligible patients who chose to participate in the study will receive the same treatment. During the radical prostatectomy procedure, but before the prostate is removed, the nerve monitor will be used to stimulate and record the nerves surrounding the prostate. After the nerve monitoring, the operation will proceed as usual. Following the surgery, patients will have follow up visits with the doctor as usual. At 3 months and 6 months, they will complete a questionnaire regarding their erectile function. The same questionnaire is also completed by patients before the operation.

What are the possible benefits and risks of participating?
There is no guarantee that participating patients will receive any benefits from this study. However, others may be helped by what is learned from this research.
Intraoperative nerve monitoring has a long successful clinical history in other areas of the body, and the use of the nerve monitor device during prostatectomy is not expected to add significant risk. However, nerve monitoring during prostatectomy is experimental, so the procedure could involve risks which are currently unknown. All foreseeable risks are explained to the patients before they chose to participate.

Where is the study run from?
This study is being conducted at Columbia University Medical Center and Weill Cornell Medical College. Between the two sites, 30 patients will be enrolled into the study.

When is the study starting and how long is it expected to run for?
The study is expected to start in mid-January of 2013, and will last until all participating patients have completed their 6 month follow up (around October 2013).

Who is funding the study?
Medtronic, Inc.

Who is the main contact?
The main contacts for this study are the Principal Investigators at each site:
Ketan K. Badani, M.D., Columbia University Medical Center, 161 Fort Washington Ave., New York, NY 10032
Ashutosh K. Tewari, M.D., Weill Cornell Medical College, 525 East 68th Street, Starr 900, New York, NY 10021

Contact information

Type(s)
Scientific

Contact name
Dr Ketan Badani

Contact details
Columbia University Medical Center
161 Fort Washington Ave.
New York
United States of America
10032

Additional identifiers

Protocol serial number
TD-07661

Study information

Scientific Title
Nerve monitoring during robotic radical prostatectomy: a prospective single-arm non-randomized feasibility study

Study objectives
This feasibility study aims to determine whether the use of nerve monitoring systems can aid in locating the cavernous nerves during robot-assisted radical prostatectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 05/02/2013:
1. Weill Cornell Medical College IRB, 24th December 2012, Protocol Number 1209013068
2. Columbia University Medical Center IRB, 10th January 2013, Protocol Number IRB-AAAK7758

Study design
Interventional prospective single-arm non-randomized multicenter feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Erectile Dysfunction

Interventions
The nerves surrounding the prostate will be monitored during the prostatectomy procedure (intraoperatively). Simultaneously, a functional response will be measured with a tissue oxygenation monitor. The nerve mapping procedure is expected to take 10-25 minutes. Subjects will be followed for 6 months following the surgical procedure to monitor adverse events and assess for postoperative erectile function.

Joint/Scientific contact details:
Ashutosh K. Tewari, M.D.
Weill Cornell Medical College
525 East 68th Street, Starr 900
New York, NY 10021

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Feasibility of nerve monitoring, defined as ability to record compound nerve action potentials from the cavernous nerve during surgery.

Key secondary outcome(s))
1. Feasibility of functional monitoring, defined as ability to evoke an increase in tissue oxygenation as a result of cavernous nerve stimulation during surgery.
2. Change in preoperative to postoperative erectile function, based on a patient-completed questionnaire (IIEF-5) at three months and six months.

Completion date
18/10/2013

Eligibility

Key inclusion criteria
1. Patient is a male between 18 years and 75 years of age
2. Patient was diagnosed with prostate cancer, undergoing nerve-sparing robotic radical prostatectomy
3. Patient has been informed of the nature of the study, agrees to its provisions and has provided written consent as approved by the Institutional Review Board (IRB) of the respective investigational site
4. Patient is able and willing to comply with all study requirements, including the follow-up evaluations and will return to the investigational site(s) for all required office visits
5. Patient has completed the International Index of Erectile Function (IIEF-5) questionnaire with a score of 17 or higher

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
1. Patient has a history of erectile dysfunction associated with neurologic abnormalities
2. Patient has untreated hypertension (systolic blood pressure > 160mm Hg and/or diastolic blood pressure > 100mm Hg)
3. Patient has any penile anatomical abnormalities (e.g. penile fibrosis or Peyronies disease)
4. Patient has a penile or urinary sphincter implant
5. Patient has a history of prior radiation therapy to the pelvic region
6. Patient is participating in another investigational device, biologic, or drug study and has not completed the primary endpoint(s) or if there is a potential for clinical interference beyond the primary endpoint
7. Patient with prior pelvic surgery with a potential for clinical interference with the primary study endpoint

Date of first enrolment
18/01/2013

Date of final enrolment
18/10/2013

Locations

Countries of recruitment
United States of America

Study participating centre
Columbia University Medical Center
New York
United States of America
10032

Sponsor information

Organisation
Medtronic, Inc (USA)

ROR
https://ror.org/00grd1h17

Funder(s)

Funder type
Industry

Funder Name
Medtronic, Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration