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Three-dimensional augmented reality-assisted surgery versus two-dimensional conventional robot-assisted surgery for prostate cancer

Submission date
25/09/2022

Recruitment status
No longer recruiting

Registration date
30/01/2023

Overall study status
Ongoing

Last Edited
30/01/2023

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
To date, precision surgery for prostate cancer strikes a delicate balance between oncological and functional outcomes. In recent decades, the advent of robotics has introduced an unprecedented level of precision, maximising postoperative functional outcomes in terms of continence and power, without compromising oncological outcomes, even in locally advanced diseases. However, the presence of positive surgical margins (PSM) after surgery remains an undesirable event, leading to a significant risk of biochemical disease recurrence (BCR). Therefore, intraoperative knowledge of the three-dimensional (3D) position of tumour lesions could prevent the surgeon from planning the procedure on the basis of two-dimensional (2D) preoperative images alone. In this context, we developed an engineered system to create high-quality 3D reconstructions based on multi-parametric magnetic resonance imaging (mpMRI). Hyper-Accuracy 3D reconstruction technology (HA3DTM) enables the creation of detailed 3D virtual models of the prostate by highlighting the tumour and its relationship to the prostate capsule. Moreover, we pave the way for artificial intelligence (AI) to achieve automated 3D augmented reality robot-assisted radical prostatectomy (AR-RARP) with the aim of maximising both oncological and functional outcomes. Here, we aimed to perform a clinical trial to compare 3D AI-AR-RARP versus conventional no 3D and will study the impact of this new technology on oncological and functional outcomes after surgery.

Who can participate?
Adult males eligible for radical prostatectomy

What does the study involve?
Eligible patients will be randomized into two groups using an Excel spreadsheet:
Group 1: Artificial intelligence 3D augmented reality robot-assisted radical prostatectomy
Group 2: 2D Conventional robot-assisted radical prostatectomy
Oncological and functional outcomes after surgery will be evaluated as follows:
1. The positive surgical margins rate will be assessed in the laboratory
2. Sexual function will be measured using a questionnaire
3. Urinary continence will be quantified by measuring urine leakage into an incontinence pad

over time
4. A blood test will measure the amount of the protein prostate-specific antigen in the blood to monitor the health of the prostate

What are the possible benefits and risks of participating?
Laparoscopy is a minimally invasive surgical technique that has long been used in the urological field; the advantages of minimally invasive surgery over traditional surgery are reduced postoperative pain, minimal cosmetic damage, less blood loss, shorter hospital stay, and faster return to activities. Laparoscopic surgery performed using the robotic system for Da Vinci surgery combines the advantages of minimally invasive access with the greater precision and mobility offered by robotic instruments operated by the surgeon. In recent years, the advent of new imaging technologies also used intraoperatively has proven to be potentially useful in improving surgical performance. In this specific case, the correct identification of the tumour with the aid of 3D images would lead to its selective eradication, minimising the anatomical structures deputed to continence and erection.
The operation is burdened by the general complications associated with any type of surgical procedure (thrombo-embolic complications, haemorrhagic complications, even serious ones with anaemia such as requiring transfusion of homologous blood, infectious complications, anaesthesiological complications, etc). In some cases, as in all surgical procedures with laparoscopic access, immediate conversion to traditional open surgery may be necessary if operative or anaesthesiological problems make this preferable. During a radical prostatectomy, the nerve pathways leading the erectile stimulus to the penis may be sacrificed; consequently, after surgery, erection may not be achieved without pharmacological or prosthetic aids. In any case, after the operation, ejaculation will no longer be present. Possible intraoperative complications may include haemorrhage with the need for haemotransfusion, perforation of the rectal wall with the immediate repair or temporary colostomy packing, and ureteral injuries with the subsequent need for ureteral reimplantation. Possible late complications associated with this operation may include stenosis of the urethro-vesical anastomosis, transient urinary incontinence, erectile dysfunction, lymphorrhoea and lymphoceles (sometimes with the need for drainage of the same). It is important to emphasise that all the risks described are the typical ones associated with a normal radical prostatectomy operation performed by means of classical laparoscopy. In fact, it is not possible to identify any additional risks directly related to the use of the robotic Da Vinci system compared to normal laparoscopic surgery.

Where is the study run from?
Candiolo Cancer Institute (Istituti di Ricovero e Cura a Carattere Scientifico [IRCCS]) (Italy) and as a multicenter study will involve also San Luigi Gongaza Hospital (Italy)

When is the study starting and how long is it expected to run for?
January 2022 to October 2027

Who is funding the study?
IRCCS (Italy)

Who is the main contact?
Professor Francesco Porpiglia (Italy)
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Contact information

Type(s)

Principal investigator

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Additional identifiers

Protocol serial number
IRCCS 395/2022

Study information

Scientific Title
Artificial intelligence 3D augmented reality robot-assisted radical prostatectomy versus no 3D intervention: a prospective multicenter randomized controlled trial

Acronym
RIDERS

Study objectives
Performing artificial intelligence 3D augmented reality robot-assisted radical prostatectomies leads to a reduction of positive surgical margins while preserving neurovascular bundles, with a consequent improvement not only in postoperative functional outcomes but also in oncological outcomes in comparison with conventional 2D robot-assisted radical prostatectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/07/2022, Candiolo IRCCS Ethics Committee (Strada Provinciale, 142 -KM 3.95 - 10060 Candiolo (TO), Italy; +39 (0)11 993 3321; comitato.etico@ircc.it), ref: IRCCS 395/2022

Primary study design
Interventional

Study design
Multicenter interventional randomized controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
Patients with localized prostate cancer suitable for robot-assisted radical prostatectomy will be randomized into two groups:
Group 1: Artificial intelligence 3D augmented reality robot-assisted radical prostatectomy
Group 2: 2D Conventional robot-assisted radical prostatectomy

From 60 days up to 1 day before the planned radical prostatectomy surgery the results of all tests normally prescribed for radical prostatectomy must be available for all the patients: Prostate Specific Antigen (PSA), multi-parametric prostate MRI, tomography abdomen (if indicated), SOTB (total body bone scan) if indicated, PET-prostate-specific membrane antigen (PSMA) (if indicated), international prostate symptom score (IPSS) and International Index of Erectile Function (IIEF-5) questionnaire. The patients will be randomized into two groups using an Excel randomization database (Microsoft Office Excel 2007, Redmond, WA). The surgery is performed using the Da Vinci HD robotic system following our radical prostatectomy technique. Specifically for this study, in the 3D patient group, an intrafascial nerve-sparing (NS) technique will be performed on the side of the index lesion; while contralaterally an intra-, inter- or extra-fascial NS technique will be performed depending on the clinical indication. At the end of the demolition phase, following the removal of the prostate from the surgical field, virtual images of the prostate will be automatically projected in the lodge using the AI software and will therefore be visualized by the surgeon on the monitor of the robotic console thanks to Tile-Pro. The virtual 3D model will make it possible to identify the extracapsular extension of the tumour lesion, projected at the level of the preserved neurovascular bundle. Subsequently, an initial selective excisional biopsy will be performed at the level of the suspected extracapsular extension on the neurovascular bundles as indicated by the 3D AR images. The biopsy specimens will then be sent for extemporaneous histological examination. For the no-3D group, the intra-, inter- or extra-fascial (mono- or bilateral) NS technique will be performed according to the clinical indication. From the day of surgery, patients are followed up until 24 months later.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Positive surgical margins rate measured using whole amount histopathological exam of sections 1 to 30 days postoperatively

Key secondary outcome(s)
1. Sexual function measured using the International Index of Erectile Function 5 Questionnaire at 1, 3, 6, 12, 18 and 24 months after surgery
2. Urinary continence measured by weighing protective pads before and after use to quantify the amount of urine leaked into the pad at 1, 3, 6, 12, 18 and 24 months after surgery
3. Prostate-specific antigen (PSA) levels in serum measured using a serum PSA ELISA test at 1, 3, 6, 12, 18 and 24 months after surgery

Completion date
01/10/2027

Eligibility

Key inclusion criteria
1. Signature of written informed consent and consent to use of personal data
2. Aged 40 years old and over and male
3. Preoperative MRI performed according to ESUR recommendations and reported in accordance with PiRads V.2
4. Disease with pre-operative MRI finding of bulging or radiological T3
5. Histological diagnosis of acinar prostate carcinoma at the level of the area shown on MRI
6. Absence of retroperitoneal or pelvic bulky (>3 cm) lymph node, bone or visceral metastatic lesions
7. Patients eligible for radical prostatectomy + pelvic lymphadenectomy
8. Eastern Cooperative Oncology Group Performance Status (ECOG PS) 0-1
9. Life expectancy ≥5 years
10. Patients motivated to preserve an erection and with pre-operative sexual activity with IIEF >17
11. Availability of patient's pre-operative clinical data
12. Patients must be available for protocol follow-up visits and consent to data collection

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 Years

Sex
Male

Key exclusion criteria
1. Special histotypes of prostate cancer
2. Patients with PSA >100 ng/ml at diagnosis
3. Unable to perform MRI (pacemaker wearers, claustrophobia) or MRI of inadequate quality to obtain 3D reconstruction
4. Concomitant treatment with other antineoplastic drugs including experimental endocrine therapies
5. Severe disease or concomitant uncontrolled medical condition including active and uncontrolled infections
6. Patients with dementia or psychiatric illness that would limit compliance with the requirements of the study or could prevent understanding and/or signing of informed consent

Date of first enrolment
01/09/2022

Date of final enrolment

01/09/2025

Locations

Countries of recruitment
Italy

Study participating centre
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Sponsor information

Organisation
Istituti di Ricovero e Cura a Carattere Scientifico

ROR
https://ror.org/04tfzc498

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Istituto di Ricovero e Cura a Carattere Scientifico

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are/will be available upon request from Prof. Francesco Porpiglia (porpiglia@libero.it)

IPD sharing plan summary
Available on request