ISRCTN06393679 https://doi.org/10.1186/ISRCTN06393679

LAPPRO: a trial comparing conventional open operation for prostate cancer with robot-assisted, 'minimally invasive' operation

Submission date
02/01/2008

Recruitment status
No longer recruiting

Registration date
07/02/2008

Overall study status
Completed

Last Edited
12/04/2024

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Radical prostatectomy is the surgical removal of the prostate gland. It is the most common treatment for localised prostate cancer (cancer that is just in the prostate gland). The type of surgical technique to use is debated. Laparoscopy allows a surgeon to access the inside of the abdomen (tummy) and pelvis without having to make large incisions in the skin. Robots are being increasingly used to assist with these procedures - this is known as robot-assisted laparoscopy. However, no studies have reported that it is clearly more effective than traditional open surgery. The aim of this study is to compare robot-assisted laparoscopy with open radical prostatectomy.

Who can participate?
Men aged up to 75 with localised prostate cancer.

What does the study involve?
The included patients were operated by one of the two surgical techniques (robot-assisted laparoscopy or open radical prostatectomy), not by personal or surgeon's preference, but according to the hospital where there were operated on.

What are the possible benefits and risks of participating?
The benefits of participating were that follow-up was more consistent and efforts were made to ensure that all patients who consented to participation were recalled for follow-up as planned. Another possible benefit was that all participants were asked to fill out detailed questionnaires at four time points. Before sending out questionnaires all men were contacted both by letter and by phone. Many of them found the phone call beneficial. The risks were of the general kind with any new treatment, i.e. outcomes are not known for the new technique, but as the robot-assisted laparoscopic operation had already been implemented in some of the participating hospitals, the participating men would have received that kind of treatment even without participating in the study.

Where is the study run from?
Sahlgrenska University Hospital (Sweden). The participating hospitals were: Sahlgrenska University Hospital, Göteborg; Carlanderska Sjukhemmet, Göteborg; Karolinska University Hospital/Solna and ditto Huddinge, Stockholm; Södersjukhuset, Stockholm; Capio St Göran Hospital, Stockholm; UroClinic, Stockholm; Alingsås Hospital, Alingsås; Capio Lundby Hospioyal, Götenbrg; NU Sjukvården/Uddevalla, Uddevalla; Kungsbacka Hospital, Kungsbacka; Varberg Hospital, Varberg; Helsingborg Hospital, Helsingborg; Sånes University Hospital, Malmö.

When is the study starting and how long is it expected to run for?
February 2008 to November 2011

Who is funding the study?
Sahlgrenska University Hospital and Swedish Cancer Foundation (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Sahlgrenska University Hospital ALFGBG-11314

Study information

Scientific Title

LAPPRO: LAParoscopic Prostatectomy Robot Open - a randomised, open trial of radical prostatectomy with or without lymph node dissection as part of a prospective, non-randomised, open trial comparing robot-assisted laparoscopic and open radical prostatectomy

Acronym
LAPPRO

Study objectives
Robot-assisted laparoscopic radical prostatectomy, compared with open radical prostatectomy, results in fewer patients with chronic complications such as incontinence and impotence without changes of the oncological result.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee, Göteborg, 19/10/2007, ref: 277-07

Study design
Multicentre prospective non-randomised active-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
Initial information at time of registration:
Group A: Traditional radical prostatectomy by open surgical approach
Group B: Radical prostatectomy by robot-assisted laparoscopic approach

In both groups, the patients who fulfill the inclusion criteria for the randomised trial will be allocated to prostatectomy with or without regional lymph node dissection. This randomisation will be stratified per hospital and include therefore both open and robot assisted operations.

Current information as of 02/09/2009:
Group A: Traditional radical prostatectomy by open surgical approach
Group B: Radical prostatectomy by robot-assisted laparoscopic approach

Added 03/11/2009:
An interim analysis by a committee of three independent scientists, not involved in any other sense in the LAPPRO trial, will be performed when about 400 patients have been included in the open prostatectomy group. The data manager will send data regarding the primary outcome, variable incontinence, for the two groups with and without age adjustment. Neither the principal investigator (PI), nor the deputy PI or any other individual within the actual trial steering committee or administration will have access to these interim results. The interim analysis group will be asked to give advice regarding the numbers of accrual as stated in the protocol (700 + 700) in view of the interim result and whether inclusion should continue beyond 700 individuals in each group or if accrual can safely be finished before this level and in that case give a suggestion about numbers needed. The date set for the interim analysis (based on accrual) is 1 December 2009.

Added 11/05/2010:
The interim analysis group adviced to continue the inclusion until 700 (open) + 1400 (robot) operations performed by surgeons with an experience >100 procedures. This should make it possible to report a significant difference of 5% in urinary leakage bewteen groups. The Ethical Committee has given approval for this enlarged trial population to be included.
Inclusion rate is about 110 patients per month. The prognosis shows that the accrual should be reached by October 2011.

Intervention Type
Procedure/Surgery

Primary outcome measure
Erectile dysfunction and urinary leakage within 24 months of radical prostatectomy. The evaluation of these symptoms will be through detailed self evaluation questionnaires, specifically constructed and validated for this population. The questionnaires will be answered before and 3, 12 and 24 months after the operation. Similar techniques have been used before in a large Swedish randomised trial comparing open radical prostatectomy to 'watchful waiting' in early prostate cancer.

Added 11/05/2010:
Urinary leakage as registered 12 months postoperatively.

Added 04/01/2011:
The definition of urinary incontinence used for the interim analysis was incontinence = change of pad/equivalent once daily or more. This definition will be used for the analysis of the primary end-point incontinence 12 months postoperatively.

Secondary outcome measures
1. Radicality as judged by the pathology report of the operation specimen. The report will be stratified for all including hospitals including pT stage, growth in resection line, N-stage and Gleason score
2. Oncological result judged by PSA relapse, defined as a PSA >0.2 to be determined at 3, 12 and 24 months after the operation
3. Operating time

4. Blood transfusions
5. Re-operations
6. Length of hospital stay
7. Re-admittance
8. Length of sick leave
9. Length of catheter treatment
10. Continued urinary leakage and erectile dysfunction
11. Inguinal hernia
12. Short term complications of any kind
13. Mortality and complications within 3 months, due to regional lymph node dissections
14. Self evaluated health related quality of life using a specifically constructed instrument, based on questionnaire used for the primary outcome measure. The instrument has been re-validated after revision.
15. Health economy analyses, based on variables described above and also including Quality-Adjusted Life Year (QALY) using the EuroQol (EQ-5D) instrument, at 3, 12 and 24 months
16. Long-term survival through Swedish Cancer Registry

Added 03/11/2009:
17. Learning curve and factors that influence learning of the surgical technique
18. An analysis will be performed of 'intrusive thoughts' in relation to health-related quality of life before and 3 months postoperatively for the patient population accrued by October 2009. The analyses will not include any information about the intervention group for the individual patients and thus no connection to treatment group will be made. The analyses will be made before full accrual has been reached.

Added 11/05/2010:
Some data from the database for the entire population (defined as those included over the initial 12 months of the trial inclusion period) will be used to analyse some confounding factors. Data will not be retrieved by interventional group, but only for the entire population. These analyses will be made during 2010 and the first part of 2011. This will be in order to ensure a timely reporting of results once the accrual has reached the target size.

Overall study start date
01/02/2008

Completion date
07/11/2011

Eligibility

Key inclusion criteria
Current information as of 02/09/2009:
1. Men with localised prostate cancer, stage T1-T3
2. No signs of distant metastases, i.e. stage M0
3. Prostate-Specific Antigen (PSA) <=20
4. All Gleason gradings
5. The patient should in all other aspects be judged suitable for radical prostatectomy
6. The patient must accept the potential complications with the operation
7. Age <=75 years
8. No other cancer in case history

Added 03/11/2009:
The accrual of patients includes every patient at each participating hospital, who gives informed consent, regardless of the experience of the surgeon. Thus the trial will also include patients operated by a surgeon in training (an experience of less than 100 cases). The total number of patients included will therefore surpass the numbers needed for the primary outcome variable.

Initial information at time of registration:
1. Men with localised prostate cancer, stage T1-T2
2. No signs of distant metastases, i.e. stage M0
3. Prostate-Specific Antigen (PSA) <=20
4. All Gleason gradings
5. The patient should in all other aspects be judged suitable for radical prostatectomy
6. The patient must accept the potential complications with the operation
7. Age <=75 years
8. No other cancer in case history

For the randomised substudy on regional lymph node dissection:
1. Gleason score >=7
2. PSA <15

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
4000

Total final enrolment
4003

Key exclusion criteria
Current information as of 02/09/2009:
History of earlier/other cancer (does not include basal cell cancer)

Initial information at time of registration:
1. Body Mass Index (BMI) >35
2. History of earlier/other cancer (does not include basal cell cancer)
3. Men with prostate cancer stage ≥T3
4. Distant metastases
5. PSA >20
6. Patient not suitable for laparoscopic operation
7. Age >75 years
8. Concerning the randomised study of regional lymph node dissection:
8.1. Gleason <7 och/eller
8.2. PSA ≥15

Date of first enrolment
01/02/2008

Date of final enrolment
07/11/2011

Locations

Countries of recruitment
Sweden

Study participating centre
Sahlgrenska University Hospital / Eastern (Östra)
Göteborg
Sweden
SE 413 85

Sponsor information

Organisation
Sahlgrenska University Hospital (Sweden)

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Sponsor type
Hospital/treatment centre

Website
http://www.sahlgrenska.se/en/Sahlgrenska-University-Hospital/In-English/

ROR
https://ror.org/04vgqjj36

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Sahlgrenska University Hospital, Göteborg and each participating centre (Sweden)

Funder Name
Swedish Cancer Foundation (Sweden)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/03/2011		Yes	No
Results article	results	11/09/2013		Yes	No
Results article	results	01/04/2014		Yes	No
Results article	results	16/08/2016		Yes	No
Results article	results	08/05/2019	10/05/2019	Yes	No
Results article	results	01/06/2020	29/04/2020	Yes	No
Results article		01/03/2021	22/03/2021	Yes	No
Results article		11/04/2024	12/04/2024	Yes	No