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Collaborative TeleMentoring program: assessing the impact of telementorship with the Da Vinci robot on surgical training

Submission date
06/01/2013

Recruitment status
No longer recruiting

Registration date
24/01/2013

Overall study status
Completed

Last Edited
16/11/2016

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims

One of the fastest growing areas of cancer surgery in the UK is robotic surgery. The main robotic system used is called the Da Vinci Si. We plan to show that the new national network for the NHS, linking all NHS hospitals and treatment centres (NHS N3) can deliver secure and reliable connections between Da Vinci Si consoles and video links, that it has minimal time delays that do not impact human decision making and no significant interruptions in transmission of data.

An important role of the NHS is to train the surgeons of the future. The top centres with the best surgical outcomes in the UK are often teaching hospitals and these centres are often the ones offering new and innovative treatments. We aim to show that trainee surgeons can be remotely guided by mentors, via Da Vinci consoles over the NHS N3 network, whilst at the same time being overseen by the trainers who will be physically in the same theatre. This is known as collaborative telementoring (CTM). First of all, we plan to connect four centres via the N3 and show how CTM can be used in real time between two centres. We also aim to show how the trainees learning experience is affected by CTM.

With the introduction of technology the pace of change has increased and by connecting hospitals and theatres in this way we hope that knowledge will be shared more efficiently. We believe CTM has the potential to result in reduced learning curves, shorter operation times and to help share new surgical techniques which will result in improved outcomes for patients. By improving surgical techniques and the ease with which these can be taught we can potentially reduce costs and increase patient access to the advantages of robotic surgery.

Robotic surgery can be an expensive service with initial outlay to buy the robot and further expenses to train the surgeons and the team involved. The true value of the service to the patients and the hospital is realised once the service is established, the team members are experienced and the outcomes optimized. Often different centers have different skills and interests. The areas of strength may vary with some centres recognized for their skills in completing the different types of surgery done. Other centres are recognized for their organizational skills delivering theatre efficiencies by reducing the amount of time it takes to prepare the theatre room between cases, so that the cost of delivering the service is reduced. If we identify centers with particular areas of strength and connect to other theatres via the N3 network, linking surgeons and theatre teams via video links, we believe that with a shared

collaborative approach we can impact learning curves, improve surgical outcomes and reduce costs by identifying and coordinating better ways of theatre team working.

Who can participate?
Training surgeons and mentors at the named centres of excellence involved will be chosen to participate in the study. Patients who are due to be operated on will be given the option to participate.

What does the study involve?
Patients involved in the study will be patients undergoing robotic surgery. The study is looking at the ability of network links to deliver mentorship. The operation and the surgeons who perform the operation will be the same whether or not patients consent to be involved. The operations involved will be standardised so that all participants will receive the same operation, whether they are involved or not in the study.

What are the possible benefits and risks of participating?
Having an operation in a teaching hospital often gives patients access to the latest techniques and technology. The advantages of patients getting involved to this research is that they may, through the N3 links, have access to experience that would not have otherwise been available at their hospital of treatment. The chances of interruptions or breaks in connectivity with the N3 are very small. BThealth, who manage the service, rate the connections as 99.999% reliable. However, even if the N3 network connections were interrupted, at no point would patients surgery be reliant on the connections as there is always an experienced team in the theatre. In this way we hope to give patients the advantages of shared knowledge and experience, without any compromises to what is the accepted standard of care in teaching hospitals.

Where is the study run from?
Guys Hospital, Churchill Hospital (Oxford) and Wexham Park Hospital (UK)

When is the study starting and how long is it expected to run for?
It is planned to start in April 2013 and be completed within 12 to 18 months

Who is funding the study?
Intuitive Surgical Inc. (USA)

Who is the main contact?
Justin Collins
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Contact information

Type(s)
Scientific

Contact name
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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Collaborative TeleMentoring program: assessing the impact of telementorship on training. Utilising connect software with the Da Vinci Si

Acronym
CTM trial

Study objectives
Null hypothesis: Collaborative telementoring (CTM) does not result in improvements in patient outcome, as measured by operation time, positive surgical margin (PSM) rates, LN yields, functional outcomes, complication rates, and length of stay.

Procedures included in the study will include Robotic assisted radical prostatectomy (RARP) +/- pelvic lymph node dissection (PLND), Robotic ssisted radical cystectomy (RARC) + PLND, +/- intracorporeal neobladder, Robotic assisted partial nephrectomy (RAPN) +/- zero ischaemia techniques.

Further reading:
Collins JW, Prokar Dasgupta, Roger Kirby, Inderbir Gill; Globilisation of healthcare without losing the human touch utilising the network old and new. BJU Int. 2012 Apr;109(8):1129-31.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre prospective randomised controlled parallel-group trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact justin.collins@asph.nhs.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Urological cancer surgery

Interventions
Patients will be recruited into either surgery for standard robotic surgery (Group A) or surgery supplemented by CTM (Group B), where surgeons from connected hospitals will mentor chosen stages, that will be agreed and planned before the day of surgery. At no point will patients undergo surgery in a hospital that does not have the ability to independently complete the robotic surgery.

All mentors must have completed at least 50 specific cases to qualify. Experience is graded level: 1) 50-100 cases 2) 100-250 cases 3) >250 cases. Mentees will be defined in two groups:
A) an SpR trainee or fellow on a rotation attached to the hospital for a period of one year or more or a consultant in post with experience of less than 50 robotic cases. These mentees will be involved in assessment of standard RARP or standard RARC with extended pelvic lymph node dissection.
B) An experienced robotic surgeon with experience of >50 cases who is learning a more sophisticated approach or technique e.g. RAPN incorporating a zero ischaemia technique or robotic intracorporeal neobladder.

Once mentors and mentees have been identified and paired for the relevant procedures, the mentee will be given a DVD with the operation broken down into the various stages and subsequent steps within each stage. The mentee will study the DVD and then there will be a planned teleconference via Skype video link (or equivalent) between the mentor and the mentee so that any issues or queries can be answered prior to commencing the surgery.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. Operation time, broken down into defined stages - these will be measured at the time of the operation and recorded.
2. Effect of CTM on learning curve defined outcomes

Secondary outcome measures
1. Positive surgical margin rates. - these will be recorded within 3 months from histology
2. Lymph Node (LN) yields.- these will be recorded within 3 months from histology
3. Functional outcomes (continence and erectile dysfunction rates). Will be measured at 3, 6 and 12 months.
4. Blood loss - will be recorded at time of the operation.
5. Complication rates using Clavien classification - will be recorded at 30 days and 90 days
6. Conversion rates: conversion to open surgery (as an indicator of technical difficulty). Conversion is defined as the need to use a laparotomy wound for any reason other than specimen retrieval - will be recorded at time of surgery.
7. Cost analysis of reduced learning curves - these results will come from the analysis of the times taken to complete the operations.

Overall study start date
01/04/2013

Completion date
01/08/2014

Eligibility

Key inclusion criteria
1. Male or female aged ≥18 years
2. Able to provide written informed consent
3. Diagnosis of urological cancer amenable to curative surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
280

Key exclusion criteria
1. Age <18
2. Inability to give informed consent

Date of first enrolment
01/04/2013

Date of final enrolment

01/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
11 Davis Road
Weybridge
United Kingdom
KT13 0XH

Sponsor information

Organisation
Intuitive Surgical Inc. (USA)

Sponsor details
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Sponsor type
Industry

Website
http://www.intuitivesurgical.com/

ROR
https://ror.org/05g2n4m79

Funder(s)

Funder type
Industry

Funder Name
Intuitive Surgical

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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