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Simulation in urological training and education: Transfer of skills from the simulation laboratory to the operating room

Submission date
06/10/2016

Recruitment status
No longer recruiting

Registration date
21/10/2016

Overall study status
Completed

Last Edited
19/11/2021

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Concerns about patient safety and clinical risk reduction have become a matter of national priority and are regularly reported in the national press. As services develop and treatment options become more complex, there are considerable time pressures put on consultants and senior medical staff to deliver clinical services. Shorter waiting times and higher levels of activity have increased the daily workload of hospital clinicians significantly over the past decade. This has led to a reduction in the time available to train and support surgical skills development in the next generation and to ensure all new surgeons have a high level of competency in all areas of practice. Junior surgeons should be offered the opportunity to train in a safe environment to prevent or reduce mistakes in the clinical setting. Simulation has the potential to provide such an environment, whereby surgeons can practice and master their craft on various forms of models and simulators as well fully immersive non-technical skills training. Surgeons can improve and practice their skills in a simulation environment prior to operating on patients under supervision. They can also receive detailed feedback about their performance during simulated procedures. This has the potential to improve surgical competency and patient outcomes world-wide. The aim of this study is to evaluate the effectiveness of simulation-based training in urology surgery (surgery on the urinary system).

Who can participate?
Urology trainees/residents who haven't performed more than 10 ureteroscopies (examinations of the upper urinary tract with a special camera that it passed through the urinary system).

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in a 2-3 day educational program where they are taught the basic principles of performing a ureteroscopy followed by hands-on simulation training using virtual reality simulators and models or cadavers (deceased people) where available. Those in the second group are taught how to perform the procedures in the operating room, as is standard practice. Participants in

both groups are followed for a total of 25 procedures or 18 months and their performance will be compared in order to assess which group is more capable performing the procedure and less causes less complications in patients.

What are the possible benefits and risks of participating?
Participants who receive the simulation training may benefit from improved performance in urological surgical procedures. There are no notable risks associated with this study.

Where is the study run from?
1. Guy's Hospital and British Association Urological Surgeons (UK)
2. Paracelsus Medical University (Austria)
3. SLK Kliniken, Klinikum Sindelfingen-Böblingen and Siloah St. Trudpert Klinikum (Germany)
4. University of Bern (Switzerland)
5. Sismanoglio General Hospital and Red Cross Hospital (Greece)
6. Health Sciences University Kartal Training & Research Hospital (Turkey)
7. Hokkaido University Hospital (Japan)
8. First Affiliated Hospital of Guangzhou Medical University (China)
10. Icahn School of Medicine at Mount Sinai (NY, USA)
11. Dalhousie University (NS) and University of British Columbia (Canada)

When is the study starting and how long is it expected to run for?
September 2015 to October 2019

Who is funding the study?
The Urology Foundation (UK)

Who is the main contact?
1. Dr Abdullatif Aydin (public)
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Study website
www.surgical-simulation.com/simulate

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BDM/14/15-68

Study information

Scientific Title

Simulation in Urological Training and Education (SIMULATE): A Randomised Controlled Clinical and Educational Trial to Determine the Effect of Structured Simulation-Based Surgical Training

Acronym
SIMULATE

Study objectives
Structured simulation-based training will be more effective and require less number of procedures in the operating room to achieve proficiency in a given surgical procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
King's College London, 28/04/2015, ref: BDM/14/15-68

Study design
Multi-centre prospective interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Simulation-based surgical training

Interventions
Participants will be recruited and randomized to one of two groups using block randomisation.

SBT arm: Participants will receive a 2-3 day educational intervention where they will be taught the principles of ureteroscopy followed by hands-on training through a simulation curriculum using virtual reality simulators and bench models as well as cadavers, where available. Furthermore, participants will receive integrated technical and non-technical skills training in a novel and portable full immersion simulation environment.

NSBT arm: Participants will be taught how to perform the procedures in the operating room, as is current practice.

Participants in both arms of the study will be followed for a total of 25 procedures or 18 months and their performance will be compared in order to assess which group is more proficient and less complications.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 18/10/2019:
Number of uretero(reno)scopy procedures required to achieve proficiency is measured using the generic Objective structured assessment of technical skill (OSATS) by their clinical supervisors for a total of 25 procedures, to assess and compare the learning curves of both arms.

Previous primary outcome measure:
Number of uretero(reno)scopy procedures required to achieve proficiency is measured using the generic Objective structured assessment of technical skill (OSATS) and the procedure-specific Uretero(reno)scopy assessment score (URSAS) tools at every procedure. Participants will be assessed on their uretero(reno)scopy performances using these assessment scales by their clinical supervisors for a total of 25 procedures, to assess and compare the learning curves of both arms.

Secondary outcome measures
Current secondary outcome measures as of 18/10/2019:
1. Number of intra- and post-operative complications are measured using patient notes at pre- and post-operation (48 hours)
2. Post-operative stone-free status of each patient
3. Feasibility, acceptability and educational impact of simulation-based training are assessed through qualitative and quantitative surveys designed for the purpose of this study at the end of each educational intervention delivered to the SBT arm

Previous secondary outcome measures:
1. Number of pre-, intra- and post-operative complications are measured using patient notes at pre- and post-operation (48 hours)
2. Costs are measured in GBP, taking into consideration the total cost of the available simulators
3. Feasibility, acceptability and educational impact of simulation-based training are assessed through qualitative and quantitative surveys designed for the purpose of this study at the end of each educational intervention delivered to the SBT arm

Overall study start date
08/09/2015

Completion date
30/10/2019

Eligibility

Key inclusion criteria

1. Urology trainees/residents
2. Not have independently performed more than 10 full uretero(reno)scopy procedures
3. No prior experience with structured simulation training in ureteroscopy (pportunistic simulation encounters, of no more than one hour, will be acceptable)

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
47

Total final enrolment
94

Key exclusion criteria
1. Independent performance of more than 10 full ureteroscopy procedures
2. Prior experience with structured simulation training in ureteroscopy, of more than one hour

Date of first enrolment
24/10/2016

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
Austria

Canada

China

England

Germany

Greece

Japan

Switzerland

Türkiye

United Kingdom

United States of America

Study participating centre
Guy's Hospital
Guy's and St. Thomas' NHS Foundation Trust
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Study participating centre
Paracelsus Medical University
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5020

Study participating centre
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Study participating centre
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Study participating centre
Red Cross Hospital
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Study participating centre
Klinikum Sindelfingen-Böblingen
University of Tuebingen
Tuebingen
Germany
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Study participating centre
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Guangzhou
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Study participating centre
Icahn School of Medicine at Mount Sinai
Mount Sinai West and St. Luke's Hospitals
New York
United States of America
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Study participating centre
Dalhousie University
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Sponsor type

University/education

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Charity

Funder Name
The Urology Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal by up to one year after the end of the trial.

Intention to publish date
01/05/2020

Individual participant data (IPD) sharing plan

The dataset is not available as it consists of assessment forms of participants' performance, which is considered confidential information. It will be stored in the MRC Centre for Transplantation, King's College London computers, specific to the SIMULATE trial.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/07/2020	20/03/2020	Yes	No
Results article		14/11/2021	19/11/2021	Yes	No