

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/10/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/11/2021	Condition category Surgery	<input type="checkbox"/> 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)
abdullatif.aydin@kcl.ac.uk
2. Mr Kamran Ahmed (scientific)
kamran.ahmed@kcl.ac.uk
3. Professor Prokar Dasgupta (scientific)
prokar.dasgupta@kcl.ac.uk

Contact information

Type(s)

Public

Contact name

Dr Abdullatif Aydin

ORCID ID

<https://orcid.org/0000-0002-5440-7741>

Contact details

5th Floor, Southwark Wing
Guy's Hospital
London
United Kingdom
SE1 9RT

+44 207 188 5906
abdullatif.aydin@kcl.ac.uk

Type(s)
Scientific

Contact name
Mr Kamran Ahmed

Contact details
5th Floor, Southwark Wing
Guy's Hospital
London
United Kingdom
SE1 9RT
+44 207 188 5906
kamran.ahmed@kcl.ac.uk

Type(s)
Scientific

Contact name
Prof Prokar Dasgupta

Contact details
5th Floor, Southwark Wing
Guy's Hospital
London
United Kingdom
SE1 9RT
+44 207 188 5906
prokar.dasgupta@kcl.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)

Other

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(s)

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.

Key secondary outcome(s)

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

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 (ppportunistic simulation encounters, of no more than one hour, will be acceptable)

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Austria

Canada

China

Germany

Greece

Japan

Switzerland

Türkiye

United States of America

Study participating centre**Guy's Hospital**

Guy's and St. Thomas' NHS Foundation Trust

Great Maze Pond

London

United Kingdom

SE1 9RT

Study participating centre**Paracelsus Medical University**

Strubergasse 21

Salzburg

Austria

5020

Study participating centre

SLK Kliniken

Am Gesundbrunnen 20-26
Heilbronn
Germany
74078

Study participating centre**Siloah St. Trudpert Klinikum**

Wilferdinger Str. 67
Pforzheim
Germany
75179

Study participating centre**Sismanoglio General Hospital**

Sismanogliou 37
Athens
Greece
151 26

Study participating centre**Red Cross Hospital**

Erithrou Stavrou ke Athanasaki
Athens
Greece
115 26

Study participating centre**University of Bern**

Hochschulstrasse 6
Bern
Switzerland
3012

Study participating centre**Kartal Education & Research Hospital**

Istanbul
Türkiye
34890

Study participating centre
Hokkaido University Hospital
5 Chome Kita 14 Jonishi
Kita Ward
Sapporo
Hokkaido
Japan
060-8648

Study participating centre
Klinikum Sindelfingen-Böblingen
University of Tuebingen
Tuebingen
Germany
-

Study participating centre
First Affiliated Hospital of Guangzhou Medical University
195 Dongfeng W Road
Yuxiu Qu
Guangzhou
China
510000

Study participating centre
Icahn School of Medicine at Mount Sinai
Mount Sinai West and St. Luke's Hospitals
New York
United States of America
-

Study participating centre
Dalhousie University
Halifax
Canada
-

Study participating centre
University of British Columbia
2329 West Mall

Vancouver
Canada
V6T 1Z4

Sponsor information

Organisation

King's College London

ROR

<https://ror.org/0220mzb33>

Organisation

Guy's and St. Thomas' NHS Foundation Trust

Funder(s)

Funder type

Charity

Funder Name

The Urology Foundation

Results and Publications

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?
Results article		14/11/2021	19/11/2021	Yes	No
Protocol article	protocol	01/07/2020	20/03/2020	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes