ISRCTN77929274 https://doi.org/10.1186/ISRCTN77929274

Telemedicine for the remote mentoring of damage control surgery in critically injured trauma patients

Submission date
17/02/2015

Recruitment status
No longer recruiting

Registration date
07/03/2015

Overall study status
Ongoing

Last Edited
20/12/2024

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Bleeding to death is the most preventable cause of post-traumatic death on earth. Many of these victims could be saved with relatively basic surgery if only they were in a location where surgery could be performed. Damage Control Surgery (DCS), is an approach which aims to simplify basic operations to save lives even if further surgery is required. Medical technology is fast advancing. Telemedicine is used to provide medical direction over a distance, and includes remote telementoring (RTM) where experts provide real-time remote guidance might allow non-surgeons to do DCS. Therefore this study will study numerous factors required to best support non-surgeons in the performance of life-saving techniques of resuscitation including performing DCS in the abdominal cavity. These factors will consist of the performance differences between trained surgeons and non-surgeons, the ability to remotely mentor non-surgeons, and their relative stress while doing so, and the ability to do so in stressful and difficult situations including a remote medical outpost, on board a ship, and during weightless aboard a “zero-G” aircraft. The main tools to be used will be the plastic organs and blood vessels of the Human Worn Partial Task Surgical Simulator (CutSuit) which is a hyper-realistic training tool that allows the performance of realistic surgical procedures on a simulated victim with realistic bleeding and the feel of real skin and tissue. We want to test if (a) experienced surgeons will lose less blood and experience less stress than non-surgeons and (b) whether RTM non-surgeons can be guided to perform life-saving procedures and that RTM will reduce stress even in far-forward operating bases, on-board ships, and weightlessness.

Who can participate?
Surgeons and military medical technicians.

What does the study involve?
In general, this study assesses “naïve first responders” (i.e. medical technicians) ability to pack the abdomen of a seriously injured person at risk of bleeding to death with the guidance of a surgeon though RTM. Participants are randomly allocated into one of two groups. Those in group 1 receive RTM with an experienced surgeon. Those in group 2 do not receive RTM. Each participant fills in a questionnaire about their medical training background and any surgical

training background in particular. They are also asked questions regarding any familiarity that they have with surgical simulation and, in particular, any experience of the CutSuit. They are all given a brief refresher course on hemorrhage control and how to potentially handle medical cases where the victim is bleeding to death from either a massive limb or abdomen injury. Each participant is then asked to perform hemorrhage control using either a first aid method or to perform a cut in the middle of the abdomen to gain entrance to the abdominal cavity, determine the site of the bleeding and pack within the abdominal cavity to compress this bleeding. Each participants performance is assessed according to the time taken to complete the procedure (TTTC) and the volume of shed blood (VSB). Comparisons are made within the two groups assessing different techniques for closing wounds and performing life changing procedures in different environments. We also compare the TTTC and VSB between naïve first responders and experienced surgeons and between surgeons performing in a normal gravity environment verses a weightless environment.

What are the possible benefits and risks of participating?
As with any surgical intervention, there is always a risk to the participant in self-inflicted injuries from handling scalpels, hemostatic clips, or other sharp instruments. These are similar risks to those that medical personal face when learning any invasive procedures. In order to partially mitigate these risks there will be very experienced “safety surgeons” present who will be observing for any unduly unsafe procedures that are that may place the participant at risk. The “safety surgeons” have the authority to halt the simulation and to exclude the participant from further participation at no penalty to the participant. While sharp injuries are possible there will be no risks of biocontamination as the CutSuit and fluids are completely inanimate. If the “safety surgeons” also perceive that any participant is undergoing undo physical or psychological distress they will halt the simulation and debrief the participant at no penalty to the participant. The purpose of this study is to collect data in order to further the mission of advancing resuscitative surgery in the field and “far forward situations”. This is not intended as a training exercise for the participants.

Where is the study run from?
Flight Research Laboratory, National Research Council of Canada and the Canadian Field Hospital (Ottawa Detachment)

When is the study starting and how long is it expected to run for?
October 2014 to September 2025

Who is funding the study?
1. Canadian Forces Medical Services
2. Royal College of Physicians and Surgeons of Canada

Who is the main contact?
Professor Andrew Kirkpatrick
andrew.kirkpatrick@albertahealthservices.ca

Contact information

Type(s)
Scientific

Contact name
Mr Andrew Kirkpatrick

Contact details
Trauma Services
1403 29 St NW
Calgary
Canada
T2N 2T9
+1 (0)403 944 2888
andrew.kirkpatrick@albertahealthservices.ca

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The marriage of advanced surgical simulation training with telepresence mentoring: training for damage control surgery in austere environments

Study objectives
Motivated but surgically-inexperienced first responders can be guided to perform expedited extremity wound closure and midline trauma laparotomy with visceral packing of simulated solid organ bleeding in austere environments, including weightlessness, through TM.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Calgary Conjoint Health Research Ethics Board Research Services Office, ref: REB14-0634

Study design
Incrementally progressive randomised controlled trial studies using surgical simulation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Exsanguination

Interventions
The Human Worn Partial Task Surgical Simulator (Cut Suit) is a hyper-realistic surgical training tool that allows the performance of realistic surgical procedures on simulated casualties. Real-time telementoring is a telemedicine technique that facilitates procedure naïve responders to perform complex tasks while mentored by remote experts. Responders will be required to perform potentially life-saving technical procedures:
1. Close a thigh incision with a simulated lacerated superficial femoral artery
2. Incise the midline of the cut suit, enter the peritoneal cavity and pack with standard surgical gauze to control a standardized and randomized visceral (splenic/hepatic or both) haemorrhage
3. Perform life-saving interventions and follow damage control resuscitation principals.
Telementoring will be provided through a freely-available Voice over Internet Protocol (VOIP) system (Skype) in which the first responders will wear head-mounted video-cameras allowing the remote mentor to view and guide their hand movements in real-time. Variable gravitational environments will be provided through the use of the National Research Council of Canada's (NRC) Flight Research Laboratory's (FRL) Falcon 20 research aircraft. The relative effectiveness of naïve first responder's ability to viscerally pack with TM guidance will be quantified through:
1. Comparison between the time to task completion (TTTC) and volume of shed blood (VSB) between naïve first responders (NMFRs) and board-certified general surgeons (BCGSs).
2. Comparison between the time to task completion (TTTC) and volume of shed blood (VSB) between telementored (TM) surgically inexperienced first responders (TM-SIFRs) and surgically inexperienced first responders without TM. The first responders will be randomly allocated into one of the two aforementioned groups.
3. Comparison of the resultant TTTC and VSB, in the comparative environments of 1g normal gravity and 0g weightlessness, as well as the descriptive practicality of (a) closing a serious extremity wound and (b) performing a DCS laparotomy in weightlessness. We will be using experienced surgeons who will do the procedures in weightless (0g) or on the ground (1g) and this will not be randomized, but will consist of each subject constituting their own comparison between on the ground and parabolic flight.
4. Comparison of the time to overall task completion (TTOTC) when performing suture closure of the skin only, versus abbreviated closure using the ITclamp rapid wound for (a) extremity (b) laparotomy for randomly allocated telementored (TM) surgically inexperienced first responders (TM-SIFRs) and surgically inexperienced first responders without TM.
5. Demonstration of the feasibility to conduct remotely mentored live saving procedures including damage control laparotomies between BCGSs and TM-SIFRs when the TM-SIFRs are (a) separated from the mentors by many times zones and oceans or (b) on-board a ship. We will be comparing randomly allocated telementored (TM) surgically inexperienced first responders (TM-SIFRs) and surgically inexperienced first responders without TM.

Intervention Type
Procedure/Surgery

Primary outcome measure
Volume of shed simulated blood (VSB)

Secondary outcome measures
1. Time to task completion (TTTC)
2. Adequacy of life-saving procedures
3. User satisfaction surveys
4. Physiological and biomedical response data of the users during the simulated procedures

Overall study start date
17/10/2014

Completion date
01/09/2025

Eligibility

Key inclusion criteria
1. Surgeon
2. Military medical technician

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
Unwillingness to participate

Date of first enrolment
17/10/2014

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Canada

Study participating centre
Flight Research Laboratory, National Research Council of Canada
Building U-61
1920 Research Rd
Ottawa Airport
Ottawa
Canada
K1A 0R6

Study participating centre
Canadian Field Hospital - Ottawa Detachment
National Defence
1745 Alta Vista Dr.
Ottawa
Canada
K1A 0K6

Sponsor information

Organisation
Canadian Forces Medical Services

Sponsor details
1 Canadian Field Hospital - Ottawa Detachment
National Defence
1745 Alta Vista Dr.
Ottawa
Canada
K1A 0K6

Sponsor type
Government

Organisation
Royal College of Physicians and Surgeons of Canada

Sponsor details
774 Echo Drive
Ottawa
Canada

K1S 5N8
+1 (0)613 730 8177
feedback@royalcollege.ca

Sponsor type
Other

Funder(s)

Funder type
Government

Funder Name
Canadian Forces Medical Services (Canada)

Funder Name
Royal College of Physicians and Surgeons of Canada

Results and Publications

Publication and dissemination plan
The results of all phases of the project will be presented at medical conferences for public disclosure and submitted for publication to peer reviewed medical journals

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Haemorrhage management pilot study	01/11/2015		Yes	No
Results article	Tube thoracostomy	01/08/2019		Yes	No
Results article	Haemorrhage management	07/01/2020	25/11/2020	Yes	No
Results article	Patient-performed lung ultrasound	03/01/2022	04/01/2022	Yes	No