UTSouthwestern eResearch CRIS

Medical Center

Date, Tuesday, May 6, 2025 8:36:11 AM

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07-2022-0001	07/11/2022-0001

View LCTE 3.0 Study Information

Help

1.0 Study Identification

1.1 Study Title:
Primary Triple versus Resection for AAST Grade I and II Colon Injuries: Does the Type of Repair Matter?

1.1.1 PTIM Clinical Research Number (Name Number):

1.1.1a PCT Number:

1.2 Principal Investigator:
Last, First

1.2.1 Principal Investigator Affiliation: Does this user's DTM Non-Partner hospital (from the Address 1, Address 2 fields on Contact, Work Health Resources) place require this?

1.3 DTM Faculty, or Partner Hospital Faculty?

- Adjunct/Volunteer Faculty
- Fellow
- Resident
- Staff (UTSW and Affiliated Hospitals)
- Student
- Lead PI, Not from UTSW or Partner Hospitals

Note: To document study personnel from UTSW and affiliated institutions please make sure they have a UTSW ID. If they do not have a UTSW ID please refer to the Adding Non-Employees to Oracle for Addition to UT Southwestern Study Personnel

1.3.2 Principal Investigator's Home Affiliated Institution:

- Children's Health
- Parkland Health and Hospital System
- Southwestern Medical Foundation
- Texas Health Resources
- Texas Scottish Rite Hospital for Children
- UT Southwestern Medical Center
- Other

1.4 Primary Research Coordinator:

1.5 Primary Administrative/Regulatory Contact:
Caroline D Wilson

1.6 Co-Investigators:

Last Name	First Name	Department
Fitzgerald	Collin	Surgery

1.6 Other Study Personnel:

Last Name	First Name	Department
Baker	Katherine	Surgery
Gannon	Ava	Surgery
Haider	Ashley	Surgery
Hubbard	Jarrett	Surgery
Martin	Morgan	Surgery
Moore	Thomas	Surgery

1.7 Will any study personnel outside UTSW be affiliated institutions be working on this study? (Non-UTSW Faculty, Staff, Students)
Yes

1.8 Is the study COVID-19 related?
No

1.9 Is this study an industry sponsored study that uses the UTSW COVID-19 Registry?
No

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View LCTE 3.0 Training Completion Dates and Study Roles

2.0 Training Completion Dates and Study Roles

The following information has been obtained from your current training records:

Name	HIPAA	HSP	GCP	User Profile
Principal Investigator	11/4/2014	11/4/2022	3/28/2023	UPPI000002
Faculty Sponsor	Not Required	3/8/2022	3/8/2023	UPPI000012
Primary Research Coordinator	Not Required	3/8/2022	3/8/2023	UPPI000013
Primary Administrative Contact	Not Required	3/8/2022	3/8/2023	UPPI000014

Co-Investigators Training Records:

Last Name	First Name	HIPAA	HSP	GCP	User Profile
Fitzgerald	Collin	7/29/2021	7/29/2021	7/29/2021	UPPI000001

Other Study Personnel Training Records:

Last Name	First Name	HIPAA	HSP	GCP	User Profile
Baker	Katherine	3/7/2019	1/4/2022	1/4/2022	UPPI000003
Gannon	Ava	11/23/2021	11/29/2022	11/23/2021	UPSHM0002
Haider	Ashley	8/15/2019	1/4/2022	1/4/2022	UPPI000004
Hubbard	Jarrett	10/11/2021	10/11/2021	10/11/2021	UPSHM0001
Martin	Morgan	2/1/2021	2/1/2021	2/1/2021	UPPI000005
Moore	Yolanda	12/27/2021	12/27/2021	12/21/2021	UPSHM0100

Other Study Personnel Training Records:

Last Name	First Name	HIPAA	HSP	GCP
Wilson	Caroline	3/8/2022	3/8/2022	3/8/2022

2.1 Upload a completed Faculty Sponsor Form (Word or PDF)
Name: CDM PHP-employee CTO disclosure (Form 801) or Not applicable

Name	Version
CDM PHP-employee form(1).docx	1

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View LCTE 4.0 Study Management

3.0 Study Funding and Other Support

3.1 Select appropriate funding source for this study: *(Check all that apply)*

- Industry - For Profit
- Industry - Non Profit
- Public - State Entities
- Public - Local
- Academic (including federal grant-funding)
- Internal - Departmental

3.1a Is this research, for any members of the study team, or their family members, likely to financial interest in the company funding the study or in any entity that produces or markets the device, drug, service or similar item?
No

Please note: All research personnel on the study team with a financial interest in the company funding the study must complete the Investigator Financial Disclosure Form and submit it to the Office of Technology Development. Please contact the Conflicts of Interest Committee at 214-648-1157 if you have questions regarding the Investigator Financial Disclosure Form or the Conflict of Interest Policy.

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View LCTE 4.1.0 Internal - Departmental

4.1.0 Internal - Departmental

4.1.1a Supporting Departments:

Name	Percent Effort
University of Texas Southwestern Medical Center	100

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View LCTE 5.0 Performance Sites

5.0 Performance Sites

Please note the following for affiliated performance sites: selecting the Parkland Health & Hospital System will automatically add the Parkland Memorial Hospital, Parkland Behavioral Health and Dallas County Psychiatric Hospital modules the investigator must complete. Selecting Children's Medical Center will automatically add the Children's Medical Center and Health Pavilion module.

5.1 Add all UT Southwestern affiliated performance sites:

Performance Site	Investigator	Procedures	Resources
Parkland Health & Hospital System	Yes	Yes	Yes

5.1.1 Will one of the UTSW sites listed in 5.1 be conducting Clinical Research/Studies/Staff not to be conducted/performing by contract research/vendor entities:
No

5.1.1a If "Yes" to 5.1.1, please list the Clinical Research Setting:
The Dell Children's Medical Center of Central Texas

5.1.2 Will the study involve collection of any form of support:
No

Name	Version

5.1.2.1 If applicable, please indicate the specific locations where recruitment will take place (i.e., name of clinic, inpatient unit, community event, etc.):
Trauma activations at the emergency department including the study at any location outside of the emergency department.

5.1.3a Is the consenting to rely on a non-UT Southwestern IRB? (This has been a requirement for Parkland, but is required instead at some or all of the sites in 5.1 for some studies, such as those that are cooperative group studies (For example, NCI CIRB or another CTSA approved external IRB.)
No

5.1.4 Are Non-Physicians to be a role in this study?
Yes - UTD 5.0 Study Summary

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6.0 Study Summary

6.1.1 Purpose. Describe why this research project will be carried out. Clearly state the specific objectives, specific aims, hypotheses (research questions) and rationale for the research.

Trauma is the leading cause of death in children and young adults in the United States. Abdominal trauma is the most common cause of death in children with blunt trauma. Colonic injuries are the most common abdominal injury sustained by children and adolescents following intraperitoneal penetrating mechanisms. In the years with concomitant hollow viscus injuries, colonic injuries are the most common injury. Colonic injuries are associated with significant morbidity and mortality.

6.1.2 Current Summary of Project. Provide a brief description of the study design. If applicable, include a description of the number of subjects to be enrolled, the duration of participation, if applicable, include a brief description of outcome variables and methods of analysis.

Penetrating colonic injuries in trauma is most often utilized in the setting of a destructive mechanism. Historically, the management of colonic injuries has been controversial. Primary repair of colonic injuries has been associated with increased rates of anastomotic leak, abscess, and mortality. Diversion has been associated with increased rates of wound infection, abscess, and mortality. Primary repair with diversion has been associated with increased rates of anastomotic leak, abscess, and mortality. Primary repair has been associated with decreased rates of wound infection, abscess, and mortality. Primary repair has been associated with decreased rates of anastomotic leak, abscess, and mortality. Primary repair has been associated with decreased rates of wound infection, abscess, and mortality.

Despite these guidelines, optimal timing of colostomy reversal following injury is not well established. Current literature suggests that colostomy reversal can be safely performed as early as 3 months following injury. However, the majority of patients undergo reversal at 6 months or greater following injury. Delay in colostomy reversal has been associated with increased hospital stay and increased resource use. Early reversal has been associated with increased rates of anastomotic leak. Delay in colostomy reversal has been associated with increased rates of wound infection. Delay in colostomy reversal has been associated with increased rates of abscess. Delay in colostomy reversal has been associated with increased rates of mortality.

Trauma surgeons are particularly at risk for the spread of antibiotic-resistant bacteria. Trauma patients are at risk for the presence of infectious complications in trauma patients. To this end, trauma surgeons are particularly at risk for the spread of antibiotic-resistant bacteria. Trauma patients are at risk for the presence of infectious complications in trauma patients. To this end, trauma surgeons are particularly at risk for the spread of antibiotic-resistant bacteria. To this end, trauma surgeons are particularly at risk for the spread of antibiotic-resistant bacteria.

6.1.3 Type of Study:
- Interventional (i.e. testing an intervention (e.g. survey, research)
- Observational (i.e. no intervention)

6.1.4 Identifiable Data or Biospecimens Only (without interaction with subjects):
No

6.1.4a Summarize the design and methodology of the study, identify and distinguish between prospective and retrospective components of the study, and describe the sources of data. Describe the procedures that will be used to collect and analyze data. Describe the statistical methods that will be used to analyze the data. Describe the procedures that will be used to ensure the accuracy and completeness of data collected from research records and/or subjects. Describe the procedures to be used to maintain the confidentiality of data during and after the research. Describe the procedures to be used to monitor the research, if applicable.

Trauma activations at the emergency department including the study at any location outside of the emergency department. Patients will be identified by the trauma surgeon on call. Patients will be consented by the trauma surgeon on call. Patients will be randomized to primary repair or primary repair with diversion. Patients will be followed for 30 days after discharge. Patients will be followed for 90 days after discharge. Patients will be followed for 1 year after discharge. Patients will be followed for 2 years after discharge. Patients will be followed for 5 years after discharge. Patients will be followed for 10 years after discharge. Patients will be followed for 20 years after discharge. Patients will be followed for 30 years after discharge. Patients will be followed for 40 years after discharge. Patients will be followed for

* By selecting Parkland as a study site, you acknowledge that you must obtain prior performance site approval from Parkland before beginning research at Parkland. The performance site approval is complete in Velos. More information about the performance site approval process can be found here. ☑

Site Activities: *(select all that apply)*

Recruitment: ☐

Procedures: ☐

Resources: ☑

ID: STU-2022-0081 **STU-2022-0081** View: SysAdmin Edit

Active:	☑
ID:	3
Sort Order:	55
Is Umbrella Site:	☑
Study Location Name:	Parkland Health & Hospital System
Velos Code:	181
Institution:	Parkland Health & Hospital System
Notification Recipients:	**Last Name First Name Contact Information.E-mail: Preferred.E-Mail** There are no items to display
Notification Summary:	N/A

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EAST MULTICENTER STUDY
DATA COLLECTION TOOL

Multicenter Study: Primary Repair versus Resection for AAST Grade I and II Colon Injuries: Does the Type of Repair Really Matter?

Site ID: _____
Enrolling Center: _____
Enrolling Co-investigator: _____

Demographics:

Admission date: _____ Patient number: _____ Age: _____ Gender: _____ Race: _____

BMI: _____

Pre-hospital comorbidities (check all that apply):

Hypertension: _____
Diabetes mellitus: _____
___ If yes, type (insulin dependent, non-insulin dependent, unsure)
Peripheral vascular disease: _____
Coronary artery disease: _____
Current smoker: _____
Alcohol abuse: _____
Substance abuse: _____
CVA: _____
COPD: _____
Cirrhosis: _____
Chronic kidney disease: _____
ESRD: _____
Current steroid use: _____
Current chemotherapy: _____
HIV/AIDS: _____

Admission Physiology:

HR: _____ ED SBP: _____ ED MAP: _____ ED RR: _____ ED Temp: _____ ED GCS (total): ____

Intubated (Y/N): _____ ISS: _____ AIS Abdomen: _____

Mechanism of injury (check one):

Blunt:
MVC: _____
MCC: _____
Fall: _____
Assault: _____

Ped vs. auto: _____
Other: _____

Penetrating:
GSW: _____
Stab: _____
Other: _____

Admission Labs:

Hgb: _____ Hct: _____ pH: _____ Base deficit: _____ Lactate: _____

Operative Variables:

Time to OR > 6 hours (Y/N): _____ AAST grade of colon injury (I or II): _____

Location of colon injury: _____ Fecal contamination (mild, moderate, severe): _____
Mechanism of repair (primary or resection with anastomosis): _____
_____If resection, stapled or handsewn?

Open abdomen (Y/N): _____ Total # abdominal surgeries: _____

Other intra-abdominal injuries (check all that apply):
Small bowel: _____
Stomach: _____
Pancreas: _____
Diaphragm: _____
Liver: _____
Spleen: _____
Gallbladder: _____
Kidney: _____
Bladder: _____
Other: _____

MTP activation (Y/N): _____ Total # PRBCs 1st 24 hours: _____ Total # FFP 1st 24 hours: _____

Total # platelets 1st 24 hours: _____ Total # cryo 1st 24 hours: _____ TXA (Y/N): _____

Antibiotic prophylaxis (single vs combination): _____
Names of antibiotic(s): _____

Outcomes:

Hospital LOS: _____ ICU LOS: _____ Ventilator days: _____

Hospital Disposition (check one):
Home: _____
LTAC: _____
SNF: _____
Inpatient rehab: _____
Morgue: _____
Other: _____

30-Day Mortality (Y/N): ___

Complications: (check all that apply)

MI: _____
ARDS: _____
Sepsis: _____
SSI: _____
_____ If yes, superficial, deep, or organ space?
UTI: _____
Bacteremia: _____
Pneumonia: _____
Anastomotic leak: _____
Fascial dehiscence: _____
ECF development: _____
Unplanned trip to the OR: _____
_____ If yes, operation performed?
Unplanned ICU admission: _____
_____ If yes, reason?

EAST MULTICENTER STUDY
DATA DICTIONARY

Multi-Center Study of AAST Grades I and II Colon Injuries – Data Dictionary

Data Entry Points and appropriate definitions / clarifications:

Entry space	Definition / Instructions
Standard Study Questions	
Site ID	Each site's assigned number
Enrolling Center	Name of institution where patient was treated
Enrolling Co-Investigator	Name of investigator entering in patient data
Demographics	
Admission Date	Date of hospital admission
Record Number	6-digit number starting with site ID (2-001, 2-002 etc.)
Age	Age of patient enrolled in years
Gender	Gender of patient enrolled
Race	Racial categories (per NIH standards) American Indian or Alaskan Native Asian Black or African American Native Hawaiian or Other Pacific Islander White
BMI	Body mass index, calculated from height and weight (kg/cm^2)
Pre-hospital comorbidities (check all that apply)	
Hypertension	Abnormally high blood pressure
Diabetes mellitus	A long-term metabolic disorder characterized by high blood sugar, insulin resistance, and relative lack of insulin
Peripheral vascular disease	A circulation disorder characterized by narrowing or blockage of blood vessels

Coronary artery disease	An impedance or blockage of one or more blood vessels that supplies blood to the heart
Current smoker	If patient is an active smoker at the time of initial presentation, check yes
Alcohol abuse	A pattern of drinking that results in harm to one's health, interpersonal relationships, or ability to work
Substance abuse	The harmful or hazardous use of psychoactive substances, including illicit drugs
CVA	Impaired blood flow to the brain due to an artery blockage or rupture that leads to the death of brain cells caused by lack of oxygen
COPD	Long-term lung disorder that results in pulmonary compromise
Cirrhosis	Moderate to severe liver disease and dysfunction that has associated findings such as portal hypertension, ascites, encephalopathy, or variceal disease
Chronic kidney disease	Moderate to severe kidney disease defined as a decreased GFR
ESRD	End-stage renal disease requiring dialysis
Current steroid use	Current use of any steroid medication at the time of admission
Current chemotherapy	Currently on chemotherapy for any reason at the time of admission
HIV/AIDS	Human immunodeficiency virus (HIV) damages the immune system and can progress to acquired immunodeficiency syndrome (AIDS) which eventually leads to immune system failure

Admission Physiology

ED HR	First heart rate at time of presentation (BPM)
ED SBP	First systolic blood pressure at time of presentation (mmHg)
ED MAP	First mean arterial pressure at time of presentation (mmHg)
ED RR	First respiratory rate at time of presentation
ED temp	First temperature at time of presentation (Celsius)
Intubated	Patient was intubated by pre-hospital providers or required intubation in the emergency department
ISS	Injury severity score, numerical value
AIS abdomen	Abbreviated injury score, numerical value for abdominal region

Mechanism of Injury (check one)

Blunt	Single choice for best description of blunt mechanism. Options include:

	MVC Peds (pedestrian) vs. auto Fall Assault MCC (Motorcycle Collision / Crash) Other
Penetrating	Single choice for best description of penetrating mechanism. Options include: GSW (gunshot wound) Stab Other

Admission Labs

Hgb	First hemoglobin (g/dL)
Hct	First hematocrit (%)
pH	First pH value (arterial preferred, venous acceptable if no arterial value available)
Base deficit	First base deficit on an arterial blood gas (mEq/L)
Lactate	First lactate (mmol/L)

Operative Variables

Time to OR > 6 hours	Check yes if patient was taken to the operating room more than 6 hours after time of presentation
AAST grade of colon injury (I or II)	Defined by the AAST Injury Scoring Scale I: Hematoma- contusion or hematoma without devascularization I: Laceration- partial thickness, no perforation II: Laceration- laceration <50% of circumference
Location of colon injury	List location of colon injury. Options include: Cecum Ascending colon Hepatic flexure Transverse colon Splenic flexure Descending colon Sigmoid colon
Fecal contamination	Found in the operative report, defined as mild, moderate, or severe
Mechanism of repair	Primary repair (suture repair) or resection with anastomosis. If patient underwent resection with anastomosis, please note if they had a handsewn anastomosis or a stapled anastomosis
Open abdomen	Temporary abdominal closure after initial trauma laparotomy
Total # abdominal surgeries	Total number of intra-abdominal operations the patient underwent throughout their hospitalization

Other intra-abdominal injuries (check all that apply)

Small bowel	Associated small bowel injury
Stomach	Associated gastric injury
Pancreas	Associated pancreatic injury
Diaphragm	Associated diaphragmatic injury
Liver	Associated liver injury
Spleen	Associated splenic injury
Gallbladder	Associated injury to the gallbladder
Kidney	Associated renal injury
Bladder	Associated bladder injury
Other	

MTP activation	Check yes if the massive transfusion protocol was initiated
Total # PRBCs in 1st 24 hours	Total units of packed red blood cells given within 1st 24 hours of patient's hospital course
Total # FFP in 1st 24 hours	Total units of fresh frozen plasma given within 1st 24 hours of patient's hospital course
Total # platelets in 1st 24 hours	Total units of platelets given within 1st 24 hours of patient's hospital course
Total # cryo in 1st 24 hours	Total units of cryoprecipitate given within 1st 24 hours of patient's hospital course
TXA	Check yes if tranexamic acid was given
Antibiotic prophylaxis	Antibiotics given at the start of the initial trauma laparotomy. Single drug therapy versus combination therapy with more than one agent
Names of antibiotics	List the name(s) of the antibiotics given for prophylaxis in the operating room

Outcomes

Hospital LOS	Free text entry for number of consecutive days patient hospitalized at initial admission (Day of admission = hospital day #1)
ICU LOS	Free text entry for number of days patient required admission to the intensive care unit (Day of admission = hospital day #1)
Ventilator days	Free text entry for number of days patient required mechanical ventilation (Day of admission = hospital day #1)
Hospital disposition	Select disposition of patient. Options include: Home Long term acute care facility Skilled nursing facility Inpatient rehabilitation facility Morgue Other

30-Day mortality	Check if patient expired within 30 days after discharge

Complications (check all that apply)

MI	Detection of a rise of cardiac biomarker values (preferably troponin) with at least one of the following: symptoms of ischemia, new or presume new significant ST-segment changes or new left bundle branch block, development of pathological Q waves in the EKG, imaging evidence of new loss of viable myocardium or new regional wall motion abnormality, identification of an intracoronary thrombus by angiography or autopsy
ARDS	Defined as occurring within 1 week of a known clinical insult or new or worsening respiratory symptoms. Must have new bilateral opacities, edema not explained by a cardiac source, and impaired oxygenation defined as mild 200 mmHg < PaO2/FiO2 < 300 mmHg with PEEP or CPPA >=5 H20, moderate 100 mmHg < PaO2/FiO2 < 200 mmHg with PEEP > 5 cm H2O, severe PaO2/FiO2 < 100 mmHg with PEEP or CPAP > 5 cm H20
Sepsis	Check if sepsis is documented during a patient's hospital course Severe sepsis: sepsis with associated organ dysfunction Septic shock: sepsis with hypotension or hypoperfusion despite fluid resuscitation
SSI	Defined as an infection occurring at the site of surgery within 30 days of the operation Superficial surgical site infection: infection occurring in the skin where the incision was made Deep surgical site infection: infection occurring in the tissue beneath the skin including the muscle and subcutaneous fat Organ space infection: infection in a body organ or in a space between organs
UTI	Patient must have one of the following: positive urine culture that is >= 10^5 microorganisms/mL of urine with no more than two species of microorganisms, or urine culture with 10 wbc/hpf
Bacteremia	Defined as two positive blood cultures that were drawn simultaneously
Pneumonia	Check if pneumonia reported during a patient's hospital course. Confirmed by the presence of the following after 48 hours of hospitalization - Purulent sputum - Associated systemic evidence of infection, WBC > 11,000 or < 4,000, fever > 100.4 degrees F / 38 degrees Celsius - Two or more serial chest radiographs with new or progressive and persistent infiltrate, consolidation, or cavitation - BAL with quantitative culture > 100,000 cfu/mL
Anastomotic leak	Development of a defect of the intestinal wall at the anastomotic site (including suture line or staple line) leading to a communication between the intra and extraluminal compartments

Fascial dehiscence	Separation of the fascial closure of an abdominal wound with the exposure of intraabdominal contents to the external environment
ECF development	Aberrant connection between the intra-abdominal tract and the skin
Unplanned trip to the OR	Patient taken back to the operating room for an unplanned reason. Free text operation(s) performed. Exclude pre-planned, staged, or procedures due to incidental findings
Unplanned ICU admission	Patient admitted to the intensive care unit for an unplanned reason or a decompensation. Free text reason for admission