IRB Approval – Expedited Review of New Study

To: Chad Hall

Date: July 18, 2024

Re: 024-352
Skin Closure After Infected Laparotomy (SCAIL): An EAST Multicenter Trial
Reference Number: 403260

Your new proposal was reviewed by a designated member of Baylor Scott & White Research IRB Red via expedited review.

This study was determined to be eligible for expedited review as it involves no greater than minimal risk to the subjects and fits into the following category from the 1998 approved list: Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)

This review included the following components:

Submission Components			
Form Name		**Version**	**Outcome**
Review Response Submission Form		Version 2.0	Approved
Review Response Submission Form		Version 1.0	Approved
Initial Review Submission Packet		Version 1.1	Approved
Study Application - Review by BSWRI IRB		Version 1.2	Approved
Study Document			
Title	**Version #**	**Version Date**	**Outcome**
EAST_Wound_management_protocol_V5	Version 1.0	n/a	Approved
K121883	Version 1.0	06/26/2024	Acknowledged
SCAIL data_dictionary_v1	Version 1.0	06/26/2024	Acknowledged
SCAIL data_collection_tool-v1	Version 1.0	06/26/2024	Acknowledged

Your submission has been approved. The approval period begins on 7/18/2024 and expires on 7/17/2025. Your next continuing review is scheduled for 6/17/2025.

This study is approved to be conducted at the following locations: Scott & White Clinic - Temple

The following individuals are approved as key study personnel or are acknowledged as study contacts/administrative support/department approvers: Hall, Chad; Lal, Sohan; Vargas, Richard

Waiver of consent/authorization: The IRB has waived the requirement for informed consent based on 45 CFR 46.116 (f). The IRB has 1) waived the requirement for authorization based on 45 CFR 164.512 (i) (2) (ii) and 2) determined the use of existing protected health information is necessary to do the research.

All events that occur on this study including protocol deviations, serious adverse events, unanticipated problems involving risks to subjects/others, subject complaints or other similar events must be reported to the IRB in accordance with the respective policies.

Remember that this study is approved to be conducted as presented. Any revisions to this proposal and/or any of the referenced documents must be approved by the IRB prior to being implemented. Additionally, if you wish to begin using any new documents, these must receive IRB approval prior to implementation of them in the study.

IRB approval may not be the final approval needed to begin the study. All contractual, financial or other administrative issues must be resolved through Baylor Scott & White Research Institute prior to beginning your study.

For Investigator Initiated studies that meet the requirements to be posted on www.clinicaltrials.gov; as Principal Investigator, it is your responsibility to ensure that your study is listed prior to enrolling the first subject. Instructions on fulfilling this requirement can be found in iRIS under the "Help" tab.

If you need additional assistance, please contact the IRB Specialist at 254-215-9697.

Sincerely,

Signature applied by Lauren Ellis on 07/18/2024 03:40:17 PM CDT

Eastern Association for the Surgery of Trauma
Advancing Science, Fostering Relationships, and Building Careers

EAST MULTICENTER STUDY
DATA COLLECTION TOOL

Multicenter Study: **__Skin Closure After Infected Laparotomy (SCAIL)_____**

Enrolling Center: _____
Enrolling Co-investigator: _____

Initial Demographics / Injury Variables:

Age: _____(≥18) Gender:_____ (M/F) Date of Initial Laparotomy:_____ (MM/DD/YYYY)
BMI:_____ (No decimals)

Diabetes Mellitus	YES/NO
Liver disease	YES/NO
Chronic kidney disease	YES/NO
Chronic steroid use	YES/NO
Congestive heart failure	YES/NO
Coronary artery disease	YES/NO
OSA/COPD	YES/NO
CVA/TIA	YES/NO
Cancer	YES/NO
Chemotherapy	YES/NO
Active smoker	YES/NO
Albumin <3	YES/NO

Laparotomy Indication:
- Trauma
- Emergency General Surgery

If Trauma, Mechanism of initial injury:
- Blunt: YES / NO
- Penetrating: YES / NO

ISS: _____(N/A, 0-75) AIS Head: _____ (0-5) AIS Chest: _____ (0-5)
AIS Abdomen: _____ (0-5)

Colon involvement: Yes/No

If EGS, Indication for Surgery:

Hernia	Yes/No
Obstruction	Yes/No
Perforation	Yes/No
Other	Yes/No

Colon involvement: Yes/No

Admission Lab values:

Hemoglobin: _____ (No decimals) pH: _____ (2 decimals) INR: _____ (1 decimal) Lactate: _____ (1 decimal) Base Deficit: _____(+ or -, no decimals)

Intra-operative variables:

Wound Class: III/IV
ASA Class: _____ (1-5)
Estimated blood loss:_____ (mL)
Highest intra-op temperature (Celsius):_____ (one decimal)
Any temperature <35C: YES/NO
Wound protector used: YES/NO
Intra-operative vasopressor therapy: YES/NO
Intra-operative antibiotics given: YES/NO (Type:_____)
Stoma created: YES/NO

Intra-operative resuscitation:

Intra-operative crystalloid given: _____ mL
Total Intra-operative blood products given: _____ mL
PRBC volume: _____ mL
FFP volume: _____ mL
Platelet volume: _____ mL
Intra-operative non-blood colloid given: _____ mL

Total fluid balance from OR _____ mL

Management of Fascia
Fascia closed during primary operation YES/NO
If NO, indication for use of open abdominal management (check one that best applies)
_____ Damage control
_____ To facilitate early re-exploration and urgent/emergent re-evaluation (i.e. assessment of bowel viability or ongoing contamination)
_____ Decompression of abdomen in setting of elevated ICP
_____ Other:_____

Date of fascial closure: _____ (MM/DD/YYYY)

Number of planned reoperations (takebacks):_____

Fascial closure method (check one that best applies):
_____ running looped monofilament suture
_____ running single arm monofilament suture
_____ interrupted monofilament suture
_____ running braided suture
_____ interrupted braided suture
_____ running barbed suture

Was mesh (biologic, biosynthetic, or synthetic) utilized for fascial closure reinforcement: YES/NO

What was the type of skin closure utilized (Check one)?
_____ Skin left open, heal by secondary intention
Wound vac applied: YES/NO
Frequency of dressing changes (select one): Daily / Every other day / Three times weekly / Other
_____ Skin closed with staples, incisional vac applied

Post-operative course:

Were IV or oral antibiotics utilized post-operatively (circle one): YES/NO
If yes, duration of antibiotics after initial laparotomy (days):_____
Were IV or oral antifungals utilized post-operatively (circle one): YES/NO
If yes, duration of antifungals after initial laparotomy (days):_____

Total MMEs given during hospitalization (excluding continuous infusions):_____
Total MMEs given during last 24 hours of hospitalization (excluding continuous infusions):_____

Outcomes:

Surgical Site Infection within 30 days: YES/NO

If Yes (Check one that best applies),
_____ Superficial, Days from initial laparotomy: _____
_____ Deep, Days from initial laparotomy: _____
_____ Organ space, Days from initial laparotomy: _____

Results of Fascial Closure: (check as applies)

_____ No complication
_____ Re-exploration required for:
- _____ Abdominal compartment syndrome
- _____ Abdominal sepsis
- _____ Dehiscence / Early repair failure
- _____ Other:_____

Wound healed within 30 days of initial operation? YES/NO

Date of wound closure (staples removed OR vac and/or packing discontinued):_____ (MM/DD/YYYY)

Complications: (check all that apply and list Hospital Day encountered)

_____ Fascial dehiscence HD #_____
_____ Enteric fistula HD #_____
_____ Intra-abdominal abscess / sepsis HD #_____

Hospital LOS: _____ Ventilator Days: _____ ICU LOS: _____

Mortality within 30 days (circle one): YES/NO
If Yes, date of mortality:_____ (MM/DD/YYYY)

Discharge Destination:
Home: YES/NO
Rehab : YES/NO
LTAC/SNF: YES/NO

Date of last follow up:_____ (MM/DD/YYYY)
Days from initial laparotomy to last follow up:_____

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EAST MULTICENTER STUDY
DATA DICTIONARY

Incisional Vac after Contaminated Laparotomy (ICLap) – Data Dictionary

Data Entry Points and appropriate definitions / clarifications:

Entry space	Definition / Instructions
Standard Study Questions	
Laparotomy Date	Date of initial Laparotomy
Age	Age of patient enrolled
Case Information	
Gender	Gender of Patient enrolled
BMI	Body mass index
Diabetes Mellitus	Type I or type II diabetes mellitus
Liver disease	Documented history of cirrhosis
Chronic kidney disease	Dialysis dependent
Chronic steroid use	Daily steroid use within the past 30 days
Congestive heart failure	Documented history of heart failure with/without preserved ejection fraction
Coronary artery disease	History of myocardial infarction, percutaneous coronary intervention or CABG
OSA/COPD	History of obstructive sleep apnea or chronic obstructive pulmonary disease
Cancer	Known active malignancy
Chemotherapy	Treated with chemotherapy and/or biologic therapy within 30 days
Active smoker	Daily tobacco use within 30 days
Albumin <3	Albumin obtained on admission prior to initial laparotomy
Mechanism of initial Injury	
Blunt	Single choice for best description of blunt mechanism (if penetrating mechanism proceed to next data point) Options include: MVC, Auto vs. Peds (Pedestrian), Fall, Assault, MCC (Motorcycle Collision / Crash) Machinery Other

Penetrating	Single choice for best description of penetrating mechanism. Options include: GSW (Gunshot wound) Shotgun (Shotgun wound) Stab (Stab Wound) Other
ISS	Numerical value for calculated ISS (ISS = Injury Severity Score)
AIS Head	Numerical Value for AIS body region = Head (AIS = Abbreviated Injury Score)
AIS Chest	Numerical Value for AIS body region = Chest (AIS = Abbreviated Injury Score)
AIS Abdomen	Numerical Value for AIS body region = Abdomen (AIS = Abbreviated Injury Score)

Pre-Operative Lab Values

Hemoglobin	Most recent Hemoglobin value (g/dL)
pH	Most recent pH value (arterial preffered, but venous venous value acceptable if no arterial value available)
Lactate	Most recent lactate (mmol/L)
Base Deficit	Most recent Base Deficit (mmol/L)

Intra-operative Variables

Wound Class	CDC Class III or IV only, see protocol
ASA Class	1- healthy, 2- mild systemic disease, 3- severe systemic disease, 4- severe systemic disease that is a constant threat to life, 5- moribund patient who is not expected to survive
Estimated blood loss	Blood loss from initial laparotomy in mL
Highest intra-op temperature	Highest core temperature during initial laparotomy in Celsius
Any Temp <35C	<35C at any time during initial laparotomy
Wound protector used	Ringed wound protector used during initial laparotomy
Vasopressor therapy	norepinephrine, phenylephrine, vasopressin, or epinephrine
Antibiotics given	During initial laparotomy
Stoma created	colostomy or ileostomy, loop or end

Intra-operative Resuscitation

Intra-operative crystalloid given (mL)	Recorded intra-operative crystalloid given (in mL's)
PRBC volume (mL)	PRBC (Packed Red Blood Cells) administered during the initial operation (in mL's)

FFP volume (mL)	FFP (Fresh Frozen Plasma) administered during the initial operation (in mL's)
Platelet volume (mL)	Platelet volume administered during the intitial operation (in mL's)
Total intra-operative blood products given (mL)	Total intra-operative blood products given during the initial operation (PRBC, FFP, Platelets, cryoprecipitate) (in mL's)
Intra-operative non-blood colloid given (mL)	Total intra-operative non-blood colloid given during the initial operation (albmumin, hespan hextend or other colloid) (in mL)
Total fluid balance from OR	Total fluid administered (crystalloid, blood product, and colloid) – intra-operative blood loss (in mL). If a negative number annotate with a negative (-) sign

Damage control indicators present during operation

Clinical coagulopathy	Clinical (not laboratory) assessment of clinical coagulopathy during initial operation (persistent non-surgical bleeding, etc.) – Check if present
Acidosis	Acidosis defined as pH <7.35 during operation Check if present
Lowest pH	Lowest recorded pH during operation – Free text entry of value.
Hypothermia	Hypothermia (defined as intra-operative Temperature < 35.0 Celsius) – Check if present

Management of Fascia

Fascial closure	Definitive closure of abdominal fascia with suture
Planned reoperations	Number of planned laparotomy re-openings after initial operation (takebacks)

Skin Closure

Secondary intention	Skin left open with or without negative pressure wound vac therapy
Incisional vac	Skin closed with staples, negative pressure vac placed over staples

Post-operative Course

Antibiotic duration	Consecutive days from date of initial laparotomy
Antifungal duration	Consecutive days from date of initial laparotomy
MMEs	Morphine milligram equivalents

Outcomes

Surgical site infection	Within 30 days from initial laparotomy; superficial/deep/organ space- see protocol for definitions of each
Re-exploration	Unplanned return to the OR for re-opening of laparotomy
Dehiscence	Spontaneous fascial opening after closure
Wound healed	Staple removal in closed incisions OR complete discontinuation of vac and packing material in open wounds
Enteric fistula	Spontaneous communication of GI tract to skin level with drainage of enteric contents through wound or skin
Intra-abdominal abscess	Identified by radiologic evaluation or intra-operative exploration
Hospital LOS (days)	Free text entry for number of consecutive days patient hospitalized at initial admission (Day of admission = hospital day #1) LOS = Length of Stay
ICU LOS (days)	Free text entry of number of consecutive days patient required ICU admission (ICU = Intensive Care Unit, LOS = Length of Stay) - Day of admission = hospital day #1
Ventilator days	Free text entry for total number of days patient required mechanical ventilation (Day of admission = hospital day #1)
Mortality admission?	Drop down menu. Yes or No. Did patient expire within 30 days of
Discharge Destination	If alive: home, inpatient rehabilitation center, long term acute care/skilled nursing facility